# NTP Historical Controls Report

By Route And Vehicle

**MICE** 

May 2009

### REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male	
	M1
	М2
	М3
	Μ4
	М5
Fema	ale
	F1
	F2
	F3
	F4
	г4 F5

the data would be shown as:

	Male			<b>Female</b>	<b>)</b>
M1	M2	МЗ	F1	F2	F3
M4	M5		F4	F5	

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

## **Table of Contents**

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

#### Page: 4

Report Date:04/29/2009

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/09/02 08/24/04 04/11/02 04/15/03 02/04/03	728 730 728 730 728	50 (1) 50 (1) 50 (1) 50 (1) 50 (1)	39(688) 34(689) 34(692) 38(691) 35(702)	56.7 56.4 56.2 56.6 52.7	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene
				Fer	nale		
Battelle Columbus Laboratory	058810504 052000706 059902304 059902006 058814807	05/08/02 08/23/04 04/10/02 04/14/03 02/03/03	727 729 727 729 731	49 (5) 50 (5) 50 (5) 49 (5) 50 (5)	34(679) 38(695) 39(705) 35(705) 35(675)	65.0 66.2 64.1 64.9 63.2	Isoeugenol Kava kava extract beta-Myrcene Pulegone 3,3',4,4'-Tetrachloroazobenzene

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female	
All Organs: Benign Tumors								
		33/50 (66%) 30/50 (60%)	34/50 (68%) 30/50 (60%)	33/50 (66%)		20/49 (41%) 27/49 (55%)	26/50 (52%) 24/50 (48%)	21/50 (42%)
verall Incidence	Total	160/250 (64%)	Mean 64%	SD 3.74%	Total	118/248 (47.58%)	Mean 47.58%	SD 6.19%
All Organs: Malignant Tumors								
		20/50 (40%) 19/50 (38%)	32/50 (64%) 28/50 (56%)	30/50 (60%)		21/49 (43%) 20/49 (41%)	19/50 (38%) 13/50 (26%)	14/50 (28%)
Overall Incidence	Total	129/250 (51.6%)	Mean 51.6%	SD 11.87%	Total	87/248 (35.08%)	Mean 35.13%	SD 7.66%
#All Organs: Malignant and Benign T	umors	43/50 (86%)	47/50 (94%)	43/50 (86%)		34/49 (69%)	39/50 (78%)	30/50 (60%)
Overall Incidence	Total	38/50 (76%) 212/250 (84.8%)	41/50 (82%) Mean 84.8%	SD 6.57%	Total	40/49 (82%) 172/248 (69.35%)	29/50 (58%) Mean 69.4%	SD 10.51%
All Organs: Hemangioma			•••••					
<b>3</b>		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	2/50 (4%)
overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	4/248 (1.61%)	Mean 1.61%	SD 1.68%
All Organs: Hemangiosarcoma	•••••							
		3/50 (6%) 3/50 (6%)	6/50 (12%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 3/49 (6%)	1/50 (2%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	22/250 (8.8%)	Mean 8.8%	SD 3.9%	Total	6/248 (2.42%)	Mean 2.43%	SD 2.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Hemangiosarcoma or Her	mangioma	2/50 (69/)	8/50 (16%)	7/50 /4/9/\		1/40 (20/)	1/50 (20/)	2/50 (69/)
		3/50 (6%) 3/50 (6%)	8/50 (16%) 3/50 (6%)	7/50 (14%)		1/49 (2%) 4/49 (8%)	1/50 (2%) 1/50 (2%)	3/50 (6%)
Overall Incidence	Total	24/250 (9.6%)	Mean 9.6%	SD 4.98%	Total	10/248 (4.03%)	Mean 4.04%	SD 2.88%
#All Organs: Histiocytic Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 3/49 (6%)	3/50 (6%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	7/248 (2.82%)	Mean 2.82%	SD 3.07%
Overall Incidence	Total	0/50 (0%) 1/50 (2%) 5/250 (2%)	2/50 (4%) 1/50 (2%) Mean 2%	1/50 (2%) SD 1.41%	Total	11/49 (22%) 6/49 (12%) 32/248 (12.9%)	6/50 (12%) 2/50 (4%) Mean 12.94%	7/50 (14%) SD 6.57%
#All Organs:								
Mesothelioma: Benign, M	alignant, NO		- / / /				- ()	- ()
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignant						•••••	•••••	
_		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
All Organs: Osteosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
All Organs: Osteosarcoma or Osteom	 na							
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
drenal Cortex: Adenoma								
		3/50 (6%)	0/50 (0%)	2/50 (4%)		0/48 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/50 (2%) 9/250 (3.6%)	3/50 (6%) Mean 3.6%	SD 2.61%	Total	1/49 (2%) 2/246 (0.81%)	0/49 (0%) Mean 0.81%	SD 1.11%
drenal Cortex: Plasma Cell Tumor Malig	nant							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/48 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/246 (0%)	0/49 (0%) Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale						Fem	ale		
*Adrenal Cortex: Sarcoma		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/48	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	0/50	(0%)	0,00	(0,0)		0/49	( - · - /	0/49	(0%)	0,00	(0,0)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	0/246	(0%)	Mea	າ `0%໌	SD	0%
Adrenal Medulla: Pheochromocytoma Benign	•••••													
		0/50 1/50	(0%) (2%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 1/49	` ,	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/250	` '		0.4%	SD	0.89%	Total		(0.41%)		n 0.41%	SD	0.91%
Adrenal Medulla: Pheochromocytoma Complex		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/48		0/50	(0%)	0/50	(0%)
		0/50	(0%)		(0%)		()		0/49	` ,	0/49	(0%)		()
verall Incidence	Total	0/250	` ,	Mean		SD		Total	0/246	,		า 0%	SD	
Adrenal Medulla: Pheochromocytoma Malignai														
,		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 0/49	(0%) (0%)	0/50 1/49	(0%) (2%)	0/50	(0%)
Overall Incidence	Total	0/250	(0%)	Mean	0%	SD	0%	Total	1/246	(0.41%)	Mea	n 0.41%	SD	0.91%
Adrenal Medulla: Pheochromocytoma: Benign,														
i necemoniceytoma. Demgii,	, complex	0/50 1/50	(0%) (2%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/48 1/49	( - · - /	0/50 1/49	(0%) (2%)	0/50	(0%)
Overall Incidence	Total	1/250	` '		0.4%	CD	0.89%	Total		(0.81%)		1 0.82%	6D	1.12%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

**Female** Male \*Bone Marrow: Hemangioma 0/50 (0%)1/50 (0%)0/48 (0%)0/50 (0%)(0%)(0%)(0%)(0%)(0%)0/50 0/50 0/49 0/50 1/250 (0.4%) **Overall Incidence** Total Mean 0.4% SD 0.89% Total 0/247 (0%) Mean 0% SD 0% \*Bone Marrow: Hemangiosarcoma 0/50 (0%)2/50 (4%)0/48 (0%)0/50 (0%)(0%)0/50 (0%)(0%)1/49 (2%)0/50 (0%)**Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% Total SD 0.91% 1/247 (0.4%) Mean 0.41% \*Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)(0%)0/48 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% #Bone: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) SD 0% Mean 0% SD 0% Total Mean 0% Total 0/248 (0%)

0/50

SD 0%

0/49

0/49

0/248

Total

(0%)

(0%)

(0%)

(0%)

Mean 0%

0/50

0/50

Total

0/50

0/50

0/250

(0%)

(0%)

(0%)

#Bone: Osteoma

**Overall Incidence** 

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0/50

0/50

(0%)

(0%)

Mean 0%

0/50

SD 0%

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Bone: Osteosarcoma or Osteoma	1							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Bone: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign								
mennigionia beingii		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								••••••
g.oa mangnam		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

				M	ale						Fema	ıle		
Brain: Meningioma: Benign, Malig	nant, NOS	0/50	(00()	0/50	(00/)	0/50	(00()		0/40	(00()	0/50	(00()	0/50	(00()
		0/50 0/50	(0%) (0%)	0/50 1/50	(0%) (2%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	1/250 (0	` '		0.4%	SD	0.89%	Total		(0%)	Mear	` '	SD	0%
Brain: Schwannoma Malignant								•••••						
•		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/49	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/250 (0	0%)	Mear	0%	SD	0%	Total	0/247	(0%)	Mear	0%	SD	0%
Clitoral/Preputial Gland: Adenoma	•••••			•••••									•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 0/49	(0%) (0%)	0/49	(0%)
Overall Incidence	Total	0/250 (0	0%)	Mear	0%	SD	0%	Total	0/241	(0%)	Mear	` '	SD	0%
Clitoral/Preputial Gland: Carcinoma	•••••	•••••		•••••	•••••		•••••						•••••	
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 1/49	(0%) (2%)	0/49	(0%)
overall Incidence	Total		0%)	Mear	` '	SD	0%	Total	1/241	(0.41%)	Mear	0.41%	SD	0.91%
Clitoral/Preputial Gland: Carcinoma or Adenoma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/47 0/47	(0%) (0%)	0/49 1/49	(0%) (2%)	0/49	(0%)
Overall Incidence	Total	0/250 (0	` '	Mear	` '	SD	0%	Total	1/241	(0.41%)	Mear	0.41%	SD	0.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: CORN OIL

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/241 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) ( 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/47 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/241 (0%)	Mean 0%	SD 0%
#Esophagus:							•••••	
Squamous Cell Carcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) ( 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
Harderian Gland: Adenoma								
		8/50 (16%) 6/50 (12%)	5/50 (10%) 9 6/50 (12%)	)/50 (18%)		3/49 (6%) 7/49 (14%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
verall Incidence	Total	34/250 (13.6%)	Mean 13.6%	SD 3.29%	Total	33/248 (13.31%)	Mean 13.28%	SD 8.77%
Harderian Gland: Carcinoma			•••••					•••••
		4/50 (8%) 1/50 (2%)	0/50 (0%) 1 0/50 (0%)	/50 (2%)		1/49 (2%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.29%	Total	2/248 (0.81%)	Mean 0.82%	SD 1.12%
Harderian Gland: Carcinoma or Adenoma					•••••			
		12/50 (24%) 7/50 (14%)	5/50 (10%) 9 6/50 (12%)	)/50 (18%)		4/49 (8%) 8/49 (16%)	5/50 (10%) 14/50 (28%)	4/50 (8%)
verall Incidence	Total	39/250 (15.6%)	Mean 15.6%	SD 5.55%	Total	35/248 (14.11%)	Mean 14.1%	SD 8.48%
Harderian Gland: Sarcoma								•••••
Garooma		0/50 (0%)	()	)/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Heart: Hemangioma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	)/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Heart: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)(0%)(0%)(0%)(0%)(0%)0/50 0/50 0/49 0/49 0/247 (0%) **Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total Mean 0% SD 0% \*Heart: Sarcoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/49 (0%)0/49 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/247 (0%) Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma 0/50 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% #Intestine Large: Cecum: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) SD 0% Mean 0% SD 0% Total Mean 0% Total 0/248 (0%) #Intestine Large: Cecum: Leiomyoma (0%)0/50 (0%)0/50 0/50 0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Groups R

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female	
#Intestine Large: Colon/Rectun	n:					
,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SE	0 0% Total	0/248 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma						
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4% SE	0 0.89% Total	1/248 (0.4%) Mean 0.4%	SD 0.89%
#Intestine Small: Duodenum: Carcinoma	•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	` '	0 0% Total	0/248 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	` ,	0 0% Total	0/248 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous						
••		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)	0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	` ,	0 0% Total	0/248 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Polyp Adenomatous	•••••				• • • • • • • • • • • • • • • • • • • •			
,,		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
ntestine Small: Jejunum: Adenoma					•••••			
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/49 (0%) 1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Intestine Small: Jejunum: Carcinoma	•••••		•••••		•••••	•••••		
		0/50 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	2/50 (4%) Mean 1.2%	SD 1.79%	Total	1/248 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE
Vehicle: CORN OIL

			Male				Female	
Intestine Small: Jejunum: Hemangiosarcoma								
-		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)		SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous	•••••							
••		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspeci Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/5 0/50 (0%)	60 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/250 (0.8%)		SD 1.79%	Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%
Intestine Small: Site Unspeci Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/5 2/50 (4%)	60 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	3/250 (1.2%)	` '	SD 1.79%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18

			Male				Female	
Intestine Small: Site Unsp								
Carcinoma or Adenom	a	0/50 (0%) 0/50 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	5/250 (2%)	Mean 2%	SD 2.83%	Total	3/248 (1.21%)	Mean 1.2%	SD 1.79%
Intestine Small: Site Unsp Hemangiosarcoma								
-		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Leiomyosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 1/49 (2%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	0/49 (0%) 1/245 (0.41%)	1/49 (2%) Mean 0.41%	SD 0.91%
slets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%	Total	3/245 (1.22%)	Mean 1.22%	SD 1.82%
Kidney: Renal Tubule: Adenoma								
		1/50 (2%)	1/50 (2%)	1/50 (2%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.1%	Total	1/49 (2%) 1/245 (0.41%)	0/49 (0%) Mean 0.41%	SD 0.91%
Kidney: Renal Tubule: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma					•••••			
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%)		0/47 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	3/250 (1.2%)	0/30 (0%) Mean 1.2%	SD 1.1%	Total	1/245 (0.41%)	Mean 0.41%	SD 0.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
Kidney: Renal Tubule: Hemangioma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/245 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Maligi	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma							•••••	
onorangio caronicana		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(****)		0/49 (0%)	0/49 (0%)	,
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Liver: Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		4/50 (00/)	5/50 (400/)	5/50 /400/)		0/40 (00/)	4/50 (004)	0/70 (004)
Overall Incidence	Total	1/50 (2%) 0/50 (0%) 12/250 (4.8%)	5/50 (10%) 1/50 (2%) Mean 4.8%	5/50 (10%) SD 4.82%	Total	0/49 (0%) 0/49 (0%) 1/247 (0.4%)	1/50 (2%) 0/49 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
	10tai	12/250 (4.6%)	ivieaii 4.076			1/247 (0.4%)		
*Liver: Hepatoblastoma								
		3/50 (6%) 1/50 (2%)	0/50 (0%) 2/50 (4%)	4/50 (8%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	10/250 (4%)	Mean 4%	SD 3.16%	Total	0/247 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma								
		24/50 (48%) 22/50 (44%)	27/50 (54%) 22/50 (44%)	26/50 (52%)		11/49 (22%) 13/49 (27%)	8/50 (16%) 3/49 (6%)	6/50 (12%)
Overall Incidence	Total	121/250 (48.4%)	Mean 48.4%	SD 4.56%	Total	41/247 (16.6%)	Mean 16.62%	SD 8.13%
*Liver: Hepatocellular Carcinoma								
		8/50 (16%) 13/50 (26%)	17/50 (34%)	14/50 (28%)		3/49 (6%) 5/49 (10%)	3/50 (6%) 2/49 (4%)	1/50 (2%)
Overall Incidence	Total	72/250 (28.8%)	Mean 28.8%	SD 9.01%	Total	14/247 (5.67%)	Mean 5.68%	SD 3.04%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

.. May 2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22

				M	ale					Fema	ile		
Liver:	Hanatah												
Hepatocellular Carcinoma or	нератор	11/50	(22%)	20/50	(40%)	16/50 (32%)		3/49	(6%)	3/50	(6%)	1/50	(2%)
		13/50	(26%)	19/50	(38%)	,		5/49	(10%)	2/49	(4%)		,
overall Incidence	Total		(31.6%)		31.6%	SD 7.67%	Total	14/247	(5.67%)		5.68%		3.04%
iver:		· • • • • • • • • • • • • • • • • • • •		•••••			• • • • • • • • • • • • • • • • • • • •						
Hepatocellular Carcinoma or	Hepatoc			_									
		28/50 29/50	` '	38/50 34/50	(76%) (68%)	33/50 (66%)		13/49 17/49	` '	10/50 4/49	(20%) (8%)	7/50	(14%)
Overall Incidence	Total	29/50 162/250	(58%) (64.8%)		(66%)	SD 8.07%	Total	51/247	` ,		(8%) 1 20.68%	8D	10.4%
verali ilicidence			, ,						,				
Hepatocellular Carcinoma, H Hepatoblastoma verall Incidence	Total	30/50 29/50 165/250	(60%) (58%)	38/50 34/50 Mear	(76%) (68%) 66%	34/50 (68%) SD 7.21%	Total	13/49 17/49 51/247	(35%)	10/50 4/49 Mean	(20%) (8%) 20.68%	7/50 SD	(14%) 10.4%
∟iver: Hepatocholangiocarcinoma													
riopatoonolangiooai onionia		2/50	(4%)	4/50	(8%)	0/50 (0%)		0/49	(0%)	0/50	(0%)	0/50	(0%)
		0/50	(0%)	1/50	(2%)			0/49	(0%)	0/49	(0%)		
		0/50	(0%)	1/00	(/							SD	00/
verall Incidence	Total	7/250 (	, ,		2.8%	SD 3.35%	Total	0/247	(0%)	Mean	0%	30	0%
		7/250 (	(2.8%)	Mear	2.8%				` '				
_iver:		7/250 (	(2.8%)	Mear	2.8%				` '				
		7/250 (	(2.8%)	Mear	2.8%				` '				
Overall Incidence Liver: Hepatocholangioma		7/250 (	(2.8%)	Mear	2.8%								

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

Report Date:04/29/2009

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male	Female
*Liver: Ito Cell Tumor Benign		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Ito Cell Tumor Malignan	ıt	0/50 (0%)	0/50 (0%) 2/50 (4%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 2/30 (4/8)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8% SD 1.79%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Plasma Cell Tumor Mali		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/247 (0%) Mean 0% SD 0%
*Liver: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 1/247 (0.4%) Mean 0.4% SD 0.89%
*Lung: Adenoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/246 (0%) Mean 0% SD 0%

<sup>......</sup> \*: Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 24

Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male	Female
*Lung: Alveolar/Bronchiolar Ac	denoma	6/50 (12%)	9/50 (18%) 8/50 (16%)	%) 4/48 (8%) 2/50 (4%) 4/50 (8%)
Overall Incidence	Total	6/50 (12%) 34/250 (13.6%)	5/50 (10%) Mean 13.6% SD 3.29%	1/49 (2%) 3/49 (6%)  Total 14/246 (5.69%) Mean 5.7% SD 2.68%
*Lung: Alveolar/Bronchiolar Ca	rcinoma			
Aiveolai/Broncillolai Ca	arcinoma	2/50 (4%) 3/50 (6%)	2/50 (4%) 5/50 (10%) 3/50 (6%)	%) 0/48 (0%) 2/50 (4%) 2/50 (4%) 2/49 (4%) 0/49 (0%)
Overall Incidence	Total	15/250 (6%)	Mean 6% SD 2.45%	Total 6/246 (2.44%) Mean 2.42% SD 2.21%
*Lung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Al	veolar/Bronchiolar 7/50 (14%)	11/50 (22%) 13/50 (26%)	%) 4/48 (8%) 4/50 (8%) 6/50 (12%)
Overall Incidence	Total	9/50 (18%) 47/250 (18.8%)	7/50 (14%) Mean 18.8% SD 5.22%	3/49 (6%) 3/49 (6%)
*Lung: Fibrosarcoma				
Overall Incidence	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/49 (0%)
Overall incidence	Total	0/250 (0%)	Weari 0% SD 0%	Total 0/246 (0%) Mean 0% SD 0%
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	) 0/48 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%	) 0/48 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) Total 0/246 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malig	nant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 26 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male		Female
#Lymph Node: Hemangiosarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node: Plasma Cell Tumor Malign	ant				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node: Sarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0%	Total 0/248 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Mast Cell Tumor Malignant	•••••					•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma						•••••		
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

telected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malig	jnant							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoacanthoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Adenoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

III. May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma	1							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
#Mammary Gland: Fibroadenoma			•••••	•••••	•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma	ı or Adenoma				• • • • • • • • • • • • • • • • • • • •			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Mesentery: Fibrosarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	0/30 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30

			Male				Female	
Mesentery: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Nose:								
Mast Cell Tumor Maligna	ant	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, 7 Papilloma Squamous or	Гongue, Phary		•••••	•••••		•••••		•••••
•	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

	Male							Female						
Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth,	Gingiva):											
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
verall Incidence	Total	1/250			0.4%	SD	0.89%	Total		(0%)	Mear	` '	SD	0%
									• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •		• • • • • • • • • • • • • • • • • • • •	
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma														
		0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)	1/50	(2%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
verall Incidence	Total	1/250	` '		0.4%	SD	0.89%	Total	0/248	, ,	Mear		SD	0%
													• • • • • • • • • • • • • • • • • • • •	
Ovary: Choriocarcinoma									0/40	(00/)	0/40	(00/)	0/50	(00/)
									0/48 0/49	(0%) (0%)	0/49 0/49	(0%) (0%)	0/50	(0%)
verall Incidence								Total	0/245	(0%)	Mear	n 0%	SD	0%
													• • • • • • • • • • • • • • • • • • • •	
Ovary: Cystadenoma														
									3/48 1/49	(6%) (2%)	5/49 2/49	(10%) (4%)	2/50	(4%)
verall Incidence								Total		(5.31%)		5.32%	SD	3.11%
Ovary: Fibrous Histiocytoma														
-									0/48 0/49	(0%) (0%)	0/49 0/49	(0%) (0%)	0/50	(0%)
									0/49	(0 /0)	0/43	(0/0)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

#### **Toxicology Data Management System**

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

	Male	Female							
*Ovary: Granulosa Cell Tumor Benign									
Granulosa Celi Tumor Benign			0/49 (0%) 0/50 (0%)						
Overall Incidence	Total	1/49 (2%) 1/245 (0.41%)	0/49 (0%) Mean 0.41% SD 0.91%						
		,							
*Ovary:									
Granulosa Cell Tumor Malignant		0/48 (0%)	0/49 (0%) 0/50 (0%)						
Overall Incidence	Tatal	` '	0/49 (0%)						
Overall Incidence	Total	0/245 (0%)	Mean 0% SD 0%						
*Ovary:									
Granulosa Cell Tumor: Benign, Malignant, NOS		0/48 (0%)	0/49 (0%) 0/50 (0%)						
		1/49 (2%)	0/49 (0%)						
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41% SD 0.91%						
*Ovary:									
Hemangioma		0/49 (00/)	0/49 (0%) 0/50 (0%)						
		0/48 (0%) 1/49 (2%)	0/49 (0%) 0/50 (0%) 1/49 (2%)						
Overall Incidence	Total	2/245 (0.82%)	Mean 0.82% SD 1.12%						
*Outen::									
*Ovary: Hemangiosarcoma									
			0/49 (0%) 0/50 (0%) 0/49 (0%)						
Overall Incidence	Total	1/245 (0.41%)	Mean 0.41% SD 0.91%						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 33 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Vehicle: CORN OIL

Length of Study: CHRONIC

	Male			Female	
*Ovary: Leiomyosarcoma					
			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary:					
Luteoma			0/48 (0%) 0/49 (0%)	1/49 (2%) 0/49 (0%)	1/50 (2%)
Overall Incidence		Total	2/245 (0.82%)	0/49 (0%) Mean 0.81%	SD 1.11%
*Ovary:				•••••	
Plasma Cell Tumor Malignant			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
*Ovary:					
Teratoma Benign			0/48 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/49 (0%) 1/245 (0.41%)	1/49 (2%) Mean 0.41%	SD 0.91%
*Ovary: Teratoma Malignant					
			0/48 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence		Total	0/245 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 34

Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Ovary: Tubulostromal Adenoma								
						0/48 (0%)	0/49 (0%)	0/50 (0%)
verall Incidence					Total	0/49 (0%) 0/245 (0%)	0/49 (0%) Mean 0%	SD 0%
veran meldence					Total	0/243 (0/0)	Wicaii 070	OD 070
Pancreas: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
		` ,				, ,		
Pancreas: Carcinoma								•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/49 (0%)	05.00/
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
ancreas: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
venell le siden se	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/49 (0%)	0/49 (0%)	CD 00/
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis o Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		4/47 (9%)	2/50 (4%)	1/50 (2%)
	T-1-1	0/50 (0%)	0/49 (0%)	00.00/	T-1-1	2/49 (4%)	1/49 (2%)	00.0000
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Page: 35 Tumor Incidence for Selected Control Animal Groups Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma	talis or Unspecif	fied Site:						
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dist Carcinoma or Adenom	talis or Unspecif			•••••				
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%)		4/47 (9%) 2/49 (4%)	2/50 (4%) 1/49 (2%)	1/50 (2%)
verall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.13%	SD 2.65%
Pituitary Gland: Pars Inte Adenoma	ermedia:							
		0/50 (0%) 0/50 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%
Pituitary Gland: Pars Inte Carcinoma or Adenom	ermedia:							
		0/50 (0%) 0/50 (0%)	1/49 (2%) 0/49 (0%)	0/49 (0%)		0/47 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	1/247 (0.4%)	Mean 0.41%	SD 0.91%	Total	1/245 (0.41%)	Mean 0.4%	SD 0.89%
Prostate: Adenoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 36 Report Date:04/29/2009

Species: MICE

Contract/Lab: All Laboratories

Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)				
overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%				
Prostate: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Salivary Glands: Carcinoma or Adenoma					•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Salivary Glands: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

. May 2000

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
Seminal Vesicle: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Fibrosarcoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Myxosarcoma			•••••					
Myxosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	3/50 (6%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 38

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma o	r Rhabdomyom	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	3/50 (6%)	0/50 (0%)
Oursell best laws	T-1-1	1/50 (2%)	0/50 (0%)	00.000/	T. ()	0/49 (0%)	2/50 (4%)	OD 0.000/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	5/248 (2.02%)	Mean 2%	SD 2.83%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
	. 0	0,200 (0,0)		02 070		0/2:0 (0/0)		02 070
#Skin: Basal Cell Adenoma or	r Basosquamou	s Tumor Benign						
	•	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal Cell Adenoma, B Trichoepithelioma	Basosquamous T	Fumor Benign, or						
monocpialenoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal Cell Carcinoma		(00)	(004)	(201)			(20)	2/20 (00)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 39 Report D

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	us Tumor (malignant	or					
,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, malign			0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
Skin:  Basal or Sq. Cell Carcil  or B), Basal Cell Adea	noma, Carcinon oma, Adenoma,	Papilloma, Sq						
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacan	noma, Carcinon oma, Adenoma,	Papilloma, Sq	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/49 (0%) 2/248 (0.81%)	0/50 (0%) 1/50 (2%) Mean 0.8%	1/50 (2%) SD 1.1%
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacan Overall Incidence Skin:	noma, Carcinon oma, Adenoma, thoma, Trichoe <sub>l</sub>	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	(,	Total	0/49 (0%)	1/50 (2%)	( 11,
Basal or Sq. Cell Carcii or B), Basal Cell Adenc Papilloma, Keratoacant Overall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoe <sub>l</sub>	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	(,	Total	0/49 (0%) 2/248 (0.81%) 	1/50 (2%) Mean 0.8% 	( 11,
Basal or Sq. Cell Carcii or B), Basal Cell Adenc Papilloma, Keratoacani verall Incidence Skin: Basosquamous Tumor	noma, Carcinon oma, Adenoma, thoma, Trichoe <sub>l</sub>	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total Total	0/49 (0%) 2/248 (0.81%)	1/50 (2%) Mean 0.8%	SD 1.1%
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacani Overall Incidence Skin: Basosquamous Tumor	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0% 0/50 (0%)		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%)	1/50 (2%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacani Overall Incidence Skin: Basosquamous Tumor Overall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (0%)		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%) 1/248 (0.4%)	1/50 (2%) Mean 0.8%  0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1%
Basal or Sq. Cell Carcii or B), Basal Cell Adend Papilloma, Keratoacani Overall Incidence Skin: Basosquamous Tumor	noma, Carcinon oma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/250 (0%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%		0/49 (0%) 2/248 (0.81%) 0/49 (0%) 0/49 (0%) 1/248 (0.4%)	1/50 (2%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1% 1/50 (2%) SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

#### Way2009

**Toxicology Data Management System**Tumor Incidence for Selected Control Animal Groups

Page: 40 Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, Myx	koma, Myxosarcoma, o	r					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%)		3/49 (6%) 2/49 (4%)	0/50 (0%) 2/50 (4 1/50 (2%)	·%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	8/248 (3.23%)	Mean 3.24% SD 2.33	3%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 1/50 (2 1/50 (2%)	!%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	3/248 (1.21%)	Mean 1.21% SD 1.19	%
Fibrosarcoma, Sarcoma, Histiocytoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 2/250 (0.8%)	0/50 (0%) 1/50 (2%) Mean 0.8%	1/50 (2%) SD 1.1%	Total	3/49 (6%) 2/49 (4%) 8/248 (3.23%)	0/50 (0%) 2/50 (4 1/50 (2%) Mean 3.24% SD 2.33	%) 3%
Skin: Fibrous Histiocytoma								• • • • • • • • • • • • • • • • • • • •
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0 0/50 (0%)	%)
		0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.41% SD 0.91	1%
Overall Incidence	Total	0/230 (0/6)	Wicaii 070			` ,		1 70
Overall Incidence #Skin: Granular Cell Tumor Ben		0/230 (076)						
#Skin:		` ,				0/49 (0%) 0/49 (0%)		%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Hemangiosarcoma								•••••
		1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	1/50 (2%)		1/49 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
#Skin: Liposarcoma					•••••			
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin:					•••••			
Myxosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin:					• • • • • • • • • • • • • • • • • • • •			
Neurofibrosarcoma or S	chwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 2/49 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 0/50 (0%)0/50 (0%)0/49 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)2/49 (4%)1/50 (2%)Overall Incidence Total 0/250 (0%) Mean 0% SD 0% Total 3/248 (1.21%) Mean 1.22% SD 1.82% #Skin: Osteosarcoma 0/50 (0%)1/50 (2%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/490/50 (0%)SD 0% Overall Incidence Total 1/250 (0.4%) Mean 0.4% SD 0.89% Total 0/248 (0%) Mean 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)1/50 3/49 (6%)0/50 (0%)1/50 (2%)(0%) (0%)(0%)0/50 0/49 0/50 (0%)Total 1/250 (0.4%) 4/248 (1.61%) **Overall Incidence** Mean 0.4% SD 0.89% Total Mean 1.62% SD 2.66% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)2/49 (4%)(2%)0/50 1/50 SD 0% **Overall Incidence** Total 0/250 (0%) Mean 0% Total 3/248 (1.21%) Mean 1.22% SD 1.82% #Skin: **Squamous Cell Carcinoma** 0/50 (0%)0/50 0/50 (0%)0/490/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% Total 0/248 (0%) Mean 0% SD 0% ......

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 43

Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Squamous Cell Carcino Basosquamous Tumor (								
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillon	na							•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon	na or Papillom	a						
	·	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon Carcinoma or Keratoaca		Squamous Cell						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Squamous Cell Papillon	na, Papilloma,							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Vehicle: CORN OIL Length of Study: CHRONIC

			Male		Female	•
#Skin: Trichoepithelioma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0		0/248 (0%) Mean	
#Skin: Sebaceous Gland: Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	
#Skin: Sebaceous Gland: Carcinoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0		0/248 (0%) Mean	
#Skin: Sebaceous Gland: Carcinoma or Adenoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	•
#Spinal Cord: Meningioma Malignant						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 0/50 (0%)	(0%)		0%) 0/50 (0%) 0%)
Overall Incidence	Total	0/250 (0%)	Mean 0% SD 0	% Total	0/248 (0%) Mean	,

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Vehicle: CORN OIL

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 45

Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

			Male	Female
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/50 (0%) 0/249 (0%)	0/50 (0%) Mean 0% SD 0%	0/49 (0%) 0/49 (0%) Total 0/244 (0%) Mean 0% SD 0%
Jveran mendence		, ,		10tal 0/244 (0/0) Wealt 0/0 05 0/0
Spleen: Hemangioma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/244 (0%) Mean 0% SD 0%
Spleen: Hemangiosarcoma				
<b>g</b>		0/50 (0%) 2/50 (4%)	2/50 (4%) 1/49 (2%) 2/50 (4%)	1/48 (2%) 0/49 (0%) 0/49 (0%) 1/49 (2%) 0/49 (0%)
Overall Incidence	Total	7/249 (2.81%)	Mean 2.81% SD 1.78%	Total 2/244 (0.82%) Mean 0.82% SD 1.13%
Spleen: Mast Cell Tumor Malignant				
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 1/49 (2%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 1/244 (0.41%) Mean 0.41% SD 0.91%
Spleen: Plasma Cell Tumor Maligna	ınt			
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/244 (0%) Mean 0% SD 0%

......

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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				Ma	ale						Fema	ıle		
Stomach, Forestomach: Mast Cell Tumor Malignant														
			(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
overall Incidence	Total	0/250 (0%	` '	Mean	` '	SD	0%	Total	0/248	` ,	Mear	` ,	SD	0%
Stomach, Forestomach: Squamous Cell Carcinoma				•••••								•••••		
•			(0%) (2%)	1/50 0/50	(2%) (0%)	0/50	(0%)		0/49 0/49	(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)
Overall Incidence	Total	2/250 (0.	` '		0.8%	SD	1.1%	Total	0/48	` ,	Mear	` '	SD	0%
Stomach, Forestomach: Squamous Cell Carcinoma Overall Incidence	or Papillon Total	0/50	(0%) (2%)	9/50 1/50 Mean	(18%) (2%) 4.4%	0/50 SD	(0%) 7.67%	Total	1/49 2/49 9/248	(2%) (4%) (3.63%)	3/50 2/50 Mear	(6%) (4%) 1 3.62%	1/50 SD	(2%) 1.67%
Stomach, Forestomach: Squamous Cell Papilloma		0/50	(004)	0/50	(400()		(00()			(004)	0/50	(00()	4/50	(00()
			(0%) (0%)	8/50 1/50	(16%) (2%)	0/50	(0%)		1/49 2/49	(2%) (4%)	3/50 2/50	(6%) (4%)	1/50	(2%)
verall Incidence	Total	9/250 (3.	6%)	Mean	3.6%	SD	6.99%	Total	9/248	(3.63%)	Mear	3.62%	SD	1.67%
Stomach, Glandular: Adenoma												•••••	•••••	
			(0%) (0%)	0/50 0/50	(0%) (0%)	0/50	(0%)		1/49 0/49	(2%) (0%)	1/50 0/50	(2%) (0%)	0/50	(0%)
	Total	0/250 (0%	` '	Mean	` '	SD		Total		(0.81%)		0.81%		1.11%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: GAVAGE Vehicle: CORN OIL Page: 47

			Male				Female	
Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/49 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/248 (0.81%)	Mean 0.81%	SD 1.11%
Testes: Adenoma	•••••							
		2/50 (4%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 3/250 (1.2%)	0/50 (0%) Mean 1.2%	SD 1.79%				
Testes:								
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%				
Thymus: Thymoma Benign								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Thymus: Thymoma Malignant								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 0/48 (0%)	0/49 (0%)
verall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	0/242 (0%)	Mean 0%	SD 0%
Гhymus: Thymoma: Benign, Malign								
		0/48 (0%) 0/49 (0%)	0/48 (0%) 0/41 (0%)	0/47 (0%)		0/47 (0%) 0/48 (0%)	0/50 (0%) 1/48 (2%)	0/49 (0%)
Overall Incidence	Total	0/233 (0%)	Mean 0%	SD 0%	Total	1/242 (0.41%)	Mean 0.42%	SD 0.93%
Thyroid Gland: Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)		0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/246 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

ol Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 0/49 (0%)	1/50 (2%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	2/246 (0.81%)	Mean 0.81%	SD 1.11%
Thyroid Gland: Follicular Cell: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 1/49 (2%)	0/50 (0%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	3/246 (1.22%)	Mean 1.22%	SD 1.83%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/48 (0%) 2/49 (4%)	0/50 (0%) 2/49 (4%)	1/50 (2%)
overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%	Total	5/246 (2.03%)	Mean 2.03%	SD 2.04%
Tissue NOS: Carcinoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Tissue NOS: Hemangiosarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 50

			Male				Female	
fTissue NOS: Plasma Cell Tumor Maligna	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
tTongue:							•••••	
Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.000/	<b>+</b>	0/49 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon	na Squamous						
-	-	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: CORN OIL

Tumor Incidence for Selected Control Animal Groups

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Contract/Lab: All Laboratories

nor incidence for Selected Contro **Route:** GAVAGE Report Date:04/29/2009

Length of Study: CHRONIC

			Male				Female	
Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	)/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/250 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Footh: Odontoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0 1/50 (2%)	)/50 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/248 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma	• • • • • • • • • • • • • • • • • • • •							
•		0/49 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Hemangiosarcoma	• • • • • • • • • • • • • • • • • • • •							
· ·		0/49 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	)/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Maligna								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0 0/50 (0%)	)/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: CORN OIL

			Male			Female		
Urinary Bladder: Sarcoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma					•••••		•••••	
Adenoma						0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
tUterus:			•••••		• • • • • • • • • • • • • • • • • • • •		•••••	
Carcinoma						0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Uterus:					• • • • • • • • • • • • • • • • • • • •		•••••	
Hemangioma						0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
Uterus:								
Hemangiosarcoma						0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/49 (0%)	0/50 (0%)	SD 0%
Overall Incidence					Total	0/248 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

**Species:** MICE **Strain:** B6C3F1

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

	Male			Female	
Jterus:					
Leiomyoma			0/49 (0%)	0/50 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	0/00 (0/0)
verall Incidence		Total	0/248 (0%)	Mean 0%	SD 0%
Jterus:					
Leiomyosarcoma					
			0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence		Total	0/49 (0%) 0/248 (0%)	0/50 (0%) Mean 0%	SD 0%
verall incluence			,		
Jterus:					
Polyp Stromal			0/40 (00/)	0/50 (40/)	0/50 (00/)
			0/49 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%)
verall Incidence		Total	2/248 (0.81%)	Mean 0.8%	SD 1.79%
Jterus:					
Sarcoma Stromal					
			1/49 (2%)	0/50 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	
verall Incidence		Total	1/248 (0.4%)	Mean 0.41%	SD 0.91%
Jterus:					
Sarcoma Stromal or Polyp Stromal					
			1/49 (2%)	2/50 (4%)	0/50 (0%)
verall lasidance		Total	0/49 (0%)	0/50 (0%)	CD 4.700/
verall Incidence		Total	3/248 (1.21%)	Mean 1.21%	SD 1.79%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Mean 0%

SD 0%

Report Date: 04/29/2009

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Schwannoma Malignant 0/49 (0%)0/50 (0%)(0%)(0%)(0%)0/49 0/50 0/248 (0%) **Overall Incidence** Total Mean 0% SD 0% #Vagina: Squamous Cell Carcinoma 0/49 (0%)0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/248 (0%) Mean 0% SD 0% #Vagina: Squamous Cell Papilloma 0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/248 (0%) Mean 0% #Zymbal's Gland: Carcinoma 0/50 (0%) (0%) (0%)0/50 (0%)0/49 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)**Overall Incidence** 0/250 (0%) Mean 0% SD 0% Mean 0% SD 0% Total Total 0/248 (0%) #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 0/50 0/49 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 0/49 (0%)0/50 (0%)

SD 0%

Total

0/248 (0%)

Total

0/250

(0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date:04/29/2009

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute	059902408 059903706 059100508	12/16/02 06/30/03 07/10/00	729 729 729	50 (1) 50 (1) 50 (1)	36(687) 40(701) 35(693)	53.8 53.9 53.6	Androstenedione alpha/beta Thujone mixture Methylene blue trihydrate
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute	059902408 059903706 059100508	12/16/02 06/30/03 07/10/00	733 731 732	50 (5) 50 (5) 50 (5)	35(690) 37(668) 29(695)	65.3 64.7 63.5	Androstenedione alpha/beta Thujone mixture Methylene blue trihydrate

Species: MICE

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Strain: B6C3F1 Length of Study: CHRONIC Vehicle: METHYLCELLULOSE

			Male				Female	
All Organs: Benign Tumors								
Overall Incidence	Total	38/50 (76%) 107/150 (71.33%)	32/50 (64%) Mean 71.33%	37/50 (74%) SD 6.43%	Total	27/50 (54%) 74/150 (49.33%)	22/50 (44%) Mean 49.33%	25/50 (50%) SD 5.03%
All Organs: Malignant Tumors						27/50 (540/)		
Overall Incidence	Total	37/50 (74%) 93/150 (62%)	30/50 (60%) Mean 62%	26/50 (52%) SD 11.14%	Total	27/50 (54%) 72/150 (48%)	19/50 (38%) Mean 48%	26/50 (52%) SD 8.72%
All Organs: Malignant and Benign Tu	mors				•••••	(000)		
Overall Incidence	Total	47/50 (94%) 138/150 (92%)	45/50 (90%) Mean 92%	46/50 (92%) SD 2%	Total	40/50 (80%) 114/150 (76%)	35/50 (70%) Mean 76%	39/50 (78%) SD 5.29%
All Organs: Hemangioma					•••••			
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%
All Organs: Hemangiosarcoma					•••••			
Overall Incidence	Total	5/50 (10%) 15/150 (10%)	4/50 (8%) Mean 10%	6/50 (12%) SD 2%	Total	1/50 (2%) 5/150 (3.33%)	1/50 (2%) Mean 3.33%	3/50 (6%) SD 2.31%
All Organs: Hemangiosarcoma or He								
Overall Incidence	Total	5/50 (10%) 15/150 (10%)	4/50 (8%) Mean 10%	6/50 (12%) SD 2%	Total	2/50 (4%) 7/150 (4.67%)	1/50 (2%) Mean 4.67%	4/50 (8%) SD 3.06%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	6/150 (4%)	Mean 4%	SD 0%
fAll Organs: Malignant Lymphoma: or Undifferentiated Cell	Histiocytic, Lyn							
Overall Incidence	Total	4/50 (8%) 10/150 (6.67%)	4/50 (8%) Mean 6.67%	2/50 (4%) SD 2.31%	Total	14/50 (28%) 26/150 (17.33%)	6/50 (12%) Mean 17.33%	6/50 (12%) SD 9.24%
All Organs: Mesothelioma: Benign,	Malignant, NO	S 0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Maligna	ınt	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteoma		0/50 /00/	4/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma		0/50 (00/)		0/50 (00)		4/50 (00/)	0(50 (004)	4/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	4/50 (09)	4/50 (20%) 0/50 (00%) 4/50 (20%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	1/50 (2%) 0/50 (0%) 1/50 (2%) Total 2/150 (1.33%) Mean 1.33% SD 1.15%
*Adrenal Cortex: Adenoma		1/50 (2%)	2/50 (4%) 5/48 (10%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	8/148 (5.41%)	Mean 5.47% SD 4.4%	0/50 (0%) 1/50 (2%) 0/50 (0%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Adrenal Cortex: Plasma Cell Tumor Malignant		0/50 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Adrenal Cortex: Sarcoma		0/50 (0%)	0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		(10)		
Overall Incidence	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) 0/48 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Adrenal Medulla: Pheochromocytoma Complex		0/40 (00/)	0/40 (00/) 0/40 (00/)	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) 0/48 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Contract/Lab: All Laboratories

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Strain: B6C3F1 Vehicle: METHYLCELLULOSE Length of Study: CHRONIC

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			Male				Female	
*Adrenal Medulla: Pheochromocytoma Mal	lignant							
Overall Incidence	Total	0/49 (0%) 1/146 (0.68%)	1/49 (2%) Mean 0.68%	0/48 (0%) SD 1.18%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Adrenal Medulla:				•••••			•••••	
Pheochromocytoma: Be	nign, Complex	0/49 (0%)	1/49 (2%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/146 (0.68%)	Mean 0.68%	SD 1.18%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Bone Marrow: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%
*Bone Marrow: Plasma Cell Tumor Maliç	gnant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Bone: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male	Female	
#Bone: Osteoma		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%	
#Bone: Osteosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 1/50 (2%)	•••••
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 2/150 (1.33%) Mean 1.33% SD 1.15%	
#Bone: Osteosarcoma or Osteoma	ı	0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 2/150 (1.33%) Mean 1.33% SD 1.15%	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	•••••
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%	
*Brain: Meningioma Benign		0/50 (00/)	0.50 (001) 0.50 (001)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%	
*Brain: Meningioma Malignant		0/50 (004)	0.50 (001)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Brain: Meningioma: Benign, Malig	gnant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Clitoral/Preputial Gland: Adenoma		0/50 (00/)	0/40 (09/)	0/50 (00/)		0/47 (00/)	0/49 /09/	0/49 (09/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/47 (0%)	0/48 (0%)	0/48 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/143 (0%)	Mean 0%	0/48 (0%) SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma	•••••			0/70 (00)				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
*Clitoral/Preputial Gland: Hemangioma					•••••			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (00/)	0/40 (00/)	0/50 (00/)		0/47 (00/)	0/49 (00/)	0/49 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/48 (0%) SD 0%
#Esophagus: Squamous Cell Carcinoma							-1	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall incluence	TOtal	0/130 (0%)	Mean 0%	3D 0%	TOLAI	0/130 (0%)	Weari 0%	3D 0%
Eye: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overall incluence	Total	0/130 (0%)	Mean 076	3D 0%	Total	0/130 (0/8)	Wearr 076	3D 0%
Harderian Gland: Adenoma								
Overall Incidence	Total	7/50 (14%) 23/150 (15.33%)	8/50 (16%) Mean 15.33%	8/50 (16%) SD 1.15%	Total	9/50 (18%) 18/150 (12%)	5/50 (10%) Mean 12%	4/50 (8%) SD 5.29%
Jveran meluence	Total	23/130 (13.33%)	WEATT 15.55%	1.15%	Total	10/100 (1270)	IVIEdII 1270	SD 3.29%
Harderian Gland: Carcinoma								
		2/50 (4%)	2/50 (4%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma		9/50 (18%)	10/50 (20%)	11/50 (22%)		10/50 (20%)	6/50 (12%)	4/50 (8%)
Overall Incidence	Total	30/150 (20%)	Mean 20%	SD 2%	Total	20/150 (13.33%)	Mean 13.33%	SD 6.11%
#Harderian Gland: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Heart: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Heart: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Heart: Sarcoma		(00)	(00)	(201)		(00)	(004)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Large: Cecum: Carcinoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Leiomyosarcoma				0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Adenoma							0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Intestine Small: Duodenum: Leiomyosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 65

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male		Female	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (00/)	0/50 (09/) 0/50	(00()	0/50 (00/) 0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Carcinoma	•••••				0/50 (00) 0/50 (00)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 Mean 0.67% SD	(0%) 1.15% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Hemangiosarcoma	•••••	0/50 (004)	0/50 (00)	(004)	0/50 (00) 0/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD	` '	0/150 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma	•••••	0.70		(90)		(00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 Mean 0.67% SD	(2%) 1.15% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma	•••••	(201)		(901)		
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 Mean 0.67% SD	(0%) 1.15% Total	0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 66

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Jejunum: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecif Adenoma	ied:							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspecif Carcinoma								
Overall Incidence	Total	3/50 (6%) 3/150 (2%)	0/50 (0%) Mean 2%	0/50 (0%) SD 3.46%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Intestine Small: Site Unspecif Carcinoma or Adenoma								
Overall Incidence	Total	3/50 (6%) 4/150 (2.67%)	0/50 (0%) Mean 2.67%	1/50 (2%) SD 3.06%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Site Unspec Hemangiosarcoma	ified:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Leiomyosarcoma			4/50 (004)	0/50 (00/)	•••••	0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Site Unspec Polyp Adenomatous	:ified:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		2/22 (191)	(20)	(201)		(20)	(201)	(201)
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	4/50 (8%) Mean 4%	0/50 (0%) SD 4%	Total	0/49 (0%) 2/143 (1.4%)	1/48 (2%) Mean 1.42%	1/46 (2%) SD 1.23%
*Islets, Pancreatic: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/46 (0%) SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma					•••••			
Overall Incidence	Total	2/50 (4%) 6/150 (4%)	4/50 (8%) Mean 4%	0/50 (0%) SD 4%	Total	0/49 (0%) 2/143 (1.4%)	1/48 (2%) Mean 1.42%	1/46 (2%) SD 1.23%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Page: 68

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%
Kidney: Renal Tubule: Carcinoma		0/50 (00/)	0/50 (00/)	4/40 /00/)		0/50 (00/)	0/50 (00/)	0(40 (00))
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma			(20)			0/20 (00)		
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) Mean 0.68%	1/49 (2%) SD 1.18%	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%
Kidney: Renal Tubule: Hemangioma		0/50 (0%)		0/49 (0%)		0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/149 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/40 /00/)		0/50 (0%)	0/50 (00/)	0/40 /00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Maligna	ınt							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 1/148 (0.68%)	1/50 (2%) Mean 0.67%	0/48 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

or incidence for Selected Contr Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

			Male	Female
*Liver: Cholangiocarcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hemangioma				
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hemangiosarcoma		2/50 (69/)	2/50 (40/) 2/50 (40/)	0/50 (00/) 4/50 (00/) 0/50 (00/)
Overall Incidence	Total	3/50 (6%) 7/150 (4.67%)	2/50 (4%) 2/50 (4%) Mean 4.67% SD 1.15%	0/50 (0%) 1/50 (2%) 0/50 (0%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Liver: Hepatoblastoma		0/50 (00())	0/50 (00)	
Overall Incidence	Total	3/50 (6%) 8/150 (5.33%)	3/50 (6%) 2/50 (4%) Mean 5.33% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Liver: Hepatocellular Adenoma				
Overall Incidence	Total	32/50 (64%) 84/150 (56%)	24/50 (48%) 28/50 (56%) Mean 56% SD 8%	14/50 (28%) 13/50 (26%) 15/50 (30%)  Total 42/150 (28%) Mean 28% SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male Female \*Liver: **Hepatocellular Carcinoma** 26/50 (52%)(32%)13/50 (26%)(10%)3/50 (6%)(10%)16/50 **Overall Incidence** Total 55/150 (36.67%) Mean 36.67% SD 13.61% Total 13/150 (8.67%) Mean 8.67% SD 2.31% \*Liver: Hepatocellular Carcinoma or Hepatoblastoma (54%)(30%)27/50 18/50 (36%)15/50 5/50 (10%)3/50 5/50 (10%)**Overall Incidence** 60/150 (40%) SD 12.49% (8.67%)SD 2.31% Total Mean 40% Total 13/150 Mean 8.67% \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 33/50 (66%)37/50 (74%) 17/50 (34%)15/50 (30%)19/50 (38%) 41/50 (82%)Overall Incidence Total 111/150 (74%) Mean 74% SD 8% Total 51/150 (34%) Mean 34% SD 4% \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (82%)33/50 (66%)38/50 17/50 (34%)15/50 (30%)19/50 (38%) 41/50 (76%)**Overall Incidence** Total 112/150 (74.67%) Mean 74.67% SD 8.08% Total 51/150 (34%) Mean 34% SD 4% \*Liver: Hepatocholangiocarcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0% \*Liver: Hepatocholangioma 0/50 (0%)(2%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%)Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

## Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Report Date:04/29/2009

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			Male				Female	
*Liver: Ito Cell Tumor Benign Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Ito Cell Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
'Liver: Plasma Cell Tumor Maligna Overall Incidence	<b>nt</b> Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
*Liver: Sarcoma						(0.00.03)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lung: Adenoma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 /00/)	0/50 /00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lung: Alveolar/Bronchiolar Adenc	oma	7/50 /4.49/ \	7/50 (4.40/)	11/50 (229/)		0/50 (00/)	2/50 /69/\	1/50 /29/)
Overall Incidence	Total	7/50 (14%) 25/150 (16.67%)	7/50 (14%) Mean 16.67%	11/50 (22%) SD 4.62%	Total	0/50 (0%) 4/150 (2.67%)	3/50 (6%) Mean 2.67%	1/50 (2%) SD 3.06%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Lung: Alveolar/Bronchiolar Card	cinoma	11/50 (22%)	6/50 (12%)	1/50 (2%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
Overall Incidence	Total	18/150 (12%)	Mean 12%	SD 10%	Total	10/150 (6.67%)	Mean 6.67%	SD 4.16%
*Lung: Alveolar/Bronchiolar Card Adenoma	cinoma or Alv	veolar/Bronchiolar						
Overall Incidence	Total	16/50 (32%) 41/150 (27.33%)	13/50 (26%) Mean 27.33%	12/50 (24%) SD 4.16%	Total	4/50 (8%) 14/150 (9.33%)	4/50 (8%) Mean 9.33%	6/50 (12%) SD 2.31%
Lung: Fibrosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma	• • • • • • • • • • • • • • • • • • • •	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/50 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Maligi	nant	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00()	4/50 (00)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Report Date:04/29/2009

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			Male				Female	
Lung: Sarcoma		0(50 (00))	0/50 (00/)	0/50 (00/)		0(50 (00))	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Fibrous Histiocytoma								
· · · · · · · · · · · · · · · · · · ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangioma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
_ymph Node:								
Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
warell lead damag	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Plasma Cell Tumor Malign	ant							
i idollid ooli Tullioi Maligii	uiii	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

......

0/50 (0%)

SD 0%

.....

0/50

Total

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

0/50

(0%)

Mean 0%

#Lymph Node: Sarcoma

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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			Male				Female	
Lymph Node, Bronchial: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 /0%/	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node, Mandibular: Hemangiosarcoma					•••••			
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
_ymph Node, Mandibular: Mast Cell Tumor Malignant	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ymph Node, Mandibular: Plasma Cell Tumor Malignant	:	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00)	4/50 (00)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
_ymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 /00/	0/50 (00/)	0/50 (00/)
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Mesenteric: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Malignan		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%
#Mammary Gland: Adenoacanthoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma		0/50 (00/)	0/50 (00)	0(50 (00))		0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Carcinoma		0/50 (00/)	0/50 (00/)	0(50 (00())		4/50 (00()	4/50 (00)	0/50 (40/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Mammary Gland: Carcinoma or Adenoma	a							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	2/50 (4%) SD 1.15%
#Mammary Gland: Fibroadenoma	•••••	0/50 (0%)	0/50 (0%)	0/50 /09/\		0/50 (00/)	0/50 (0%)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mammary Gland: Fibroma, Fibroadenom		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom			0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Mesentery: Fibrosarcoma			0/20	(00)				(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Mesentery: Hemangioma		0/50 (00()	0/50 (00/)	0/50 (00/)		0/50 /00/	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
lose:					• • • • • • • • • • • • • • • • • • • •			
Mast Cell Tumor Malig	nant							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous c	, Tongue, Phary							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcine	, Tongue, Phary	nx, Tooth, Gingiva):	•••••	•••••			•••••	
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	, Tongue, Phary				•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

	Male		Female	
*Ovary: Choriocarcinoma		0/40 (00/)	4/40 (00/)	/47 (00/)
Overall Incidence	Total	0/49 (0%) 1/144 (0.69%)	1/48 (2%) 0 Mean 0.69%	/47 (0%) SD 1.2%
*Ovary: Cystadenoma		(00)	(10)	(100)
Overall Incidence	Total	4/49 (8%) 8/144 (5.56%)	2/48 (4%) 2 Mean 5.53%	/47 (4%) SD 2.28%
*Ovary: Fibrous Histiocytoma		0/49 (0%)	0/48 (0%) 0	/47 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Benign		0/49 (0%)	0/48 (0%) 0	/47 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor Malignant		0/49 (0%)	0/48 (0%) 0	/47 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) 0 Mean 0%	/47 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 79

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Male			Female	
*Ovary: Hemangioma		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma Overall Incidence	Total	0/49 (0%) 1/144 (0.69%)	0/48 (0%) Mean 0.71%	1/47 (2%) SD 1.23%
Overall incluence	ı Olal	1/144 (0.09%)	Wearr 0.71%	3D 1.23%
*Ovary: Leiomyosarcoma Overall Incidence	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
*Ovary:				
Luteoma Overall Incidence	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
*Ovary: Plasma Cell Tumor Malignant		0/49 (0%)	1/48 (2%)	0/47 (0%)
Overall Incidence	Total	1/144 (0.69%)	Mean 0.69%	SD 1.2%
*Ovary: Teratoma Benign				
Overall Incidence	Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 80

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Ovary: Teratoma Malignant						0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence					Total	0/49 (0%)	0/48 (0%) Mean 0%	SD 0%
*Overno					•••••			
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/49 (0%) 0/144 (0%)	0/48 (0%) Mean 0%	0/47 (0%) SD 0%
*Pancreas: Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/48 (0%)	0/46 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/143 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/40 (00)	0/40 (00/)	0/40 /00/
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/49 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/46 (0%) SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/49 (0%) 0/143 (0%)	0/48 (0%) Mean 0%	0/46 (0%) SD 0%
*Pituitary Gland: Pars Distalis o	or Unspecif	ied Site:						
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/48 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/49 (2%) 4/144 (2.78%)	2/49 (4%) Mean 2.77%	1/46 (2%) SD 1.14%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:						
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)	0/50 (0%)		1/49 (2%)	2/49 (4%)	1/46 (2%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	4/144 (2.78%)	Mean 2.77%	SD 1.14%
*Pituitary Gland: Pars Interme Adenoma	edia:							
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	1/46 (2%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.72%	SD 1.26%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	1/46 (2%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	1/144 (0.69%)	Mean 0.72%	SD 1.26%
*Prostate: Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Prostate: Hemangioma		0/50 (0%)	0/49 (0%)	0/49 (0%)				
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/43 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/40 (09/)	0/40 (09/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skeletal Muscle: Fibrosarcoma		2/22 (221)			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 83

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skeletal Muscle: Myxosarcoma		0.700 (001)	0.70	(201)		(70)	(201)	0/20 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skeletal Muscle: Rhabdomyosarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skeletal Muscle: Rhabdomyosarcoma or R	thabdomyom		0/50 (00/)	0/50 (09/)		0/50 (/0//)	4/50 (20()	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skeletal Muscle: Sarcoma					•••••			
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Adenoma or B	asosquamou	•			•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
#Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma											
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%			
#Skin: Basal Cell Carcinoma		0/50 (0%)			•••••	0/50 (0%)		1/50 /29/\			
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%			
#Skin: Basal Cell Carcinoma ( NOS)	or Basosquamo	us Tumor (malignant or			••••••						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%			
#Skin: Basal Cell Carcinoma, Tumor (benign, malign			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
#Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	noma, Carcinor oma, Adenoma,	Papilloma, Sq	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)			
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%			
#Skin: Basosquamous Tumo	r Benign	0/50 (00()	0/50 (00/)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 /00/			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

0/50 (0%) 0/150 (0%) oma, <b>M</b> yxosarcoma, or	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	7/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%				
0/150 (0%)	` ,	` '	Total	` '	` '	` '	
oma. Myxosarcoma. or							
z, myxoodi ooiild, oi							
1/50 (2%)	0/50 (0%)	1/50 (2%)	Total	5/50 (10%)	3/50 (6%)	3/50 (6%) SD 2.31%	
` ,				` ,			
						3/50 (6%)	
0/150 (0%)	Mean 0%	SD 0%	Total	8/150 (5.33%)	Mean 5.33%	SD 1.15%	
ı, <b>or Fibrous</b> 1/50 (2%)	0/50 (0%)	1/50 (2%)		5/50 (10%)	3/50 (6%)	3/50 (6%)	
2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	11/150 (7.33%)	Mean 7.33%	SD 2.31%	
1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%	
	2/150 (1.33%)  0/50 (0%)  0/150 (0%)  1, or Fibrous  1/50 (2%)  2/150 (1.33%)	2/150 (1.33%) Mean 1.33%  0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0%  1, or Fibrous  1/50 (2%) 0/50 (0%) 2/150 (1.33%) Mean 1.33%  1/50 (2%) 0/50 (0%) 1/150 (0.67%) Mean 0.67%	2/150 (1.33%) Mean 1.33% SD 1.15%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0%  1, or Fibrous  1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15%  1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15%	2/150 (1.33%) Mean 1.33% SD 1.15% Total  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0% Total  1, or Fibrous  1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total  1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15% Total	2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 3/50 (6%) 0/150 (0%) Mean 0% SD 0% Total 8/150 (5.33%)  1, or Fibrous  1/50 (2%) 0/50 (0%) 1/50 (2%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%)  1/50 (2%) 0/50 (0%) 0/50 (0%) 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 (0%)	2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) Mean 7.33%  0/50 (0%) 0/50 (0%) 0/50 (0%) 3/50 (6%) 2/50 (4%) 0/150 (0%) Mean 0% SD 0% Total 8/150 (5.33%) Mean 5.33%  1, or Fibrous  1/50 (2%) 0/50 (0%) 1/50 (2%) 5/50 (10%) 3/50 (6%) 2/150 (1.33%) Mean 1.33% SD 1.15% Total 11/150 (7.33%) Mean 7.33%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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			Male				Female	
‡Skin: Hemangioma		0/50 (0%)	0/50 (09/)	0/50 (09/)		0/50 (0%)	0/50 (0%)	1/50 (20/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
≄Skin: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 3/150 (2%)	1/50 (2%) Mean 2%	1/50 (2%) SD 0%
Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Skin: Myxosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Neurofibrosarcoma or S			0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Neurofibrosarcoma, Ne malignant or NOS)	urofibroma, or	, ,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (09/)	0/50 (00/)	4/50 (20/)		4/50 (20/)	1/50 (2%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%
#Skin: Schwannoma Malignant	••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Carcinom	a							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Squamous Cell Carcinom Basosquamous Tumor (n			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Skin: Squamous Cell Papilloma	1	0/50 (00()	0/50 (00/)	0/50 (00)		0/50 /00/	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

#Skin:     Squamous Cell Papilloma, Papilloma, Squamous Cell     Carcinoma or Keratoacanthoma			male	Fem						ale	М					
Solid   Control   Contro	(0%)	0/50 //	(0%)	0/50	(0%)	0/50		(0%)	0/50	(0%)	0/50	(0%)	0/50	oma	loma or Papille	
Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)         0/50 (0%)	` '	SD 0%	` ,		` ,		Total	` ,		` '		` ,		I	Total	Overall Incidence
Description   Total   O/150 (0%)   Mean 0%   SD 0%   Total   O/150 (0%)   Mean 0%   SD 0%					•••••			•••••	•••••	•••••		s Cell	amous	na, Squ		Squamous Cell Papil
Squamous Cell Papilloma, Papilloma, or Keratoacanthoma           0/50 (0%)         0/5	(0%) 0%	0/50 (0 SD 0%	` ,		` ,		Total	` ,		` '		` ,		I	Total	Overall Incidence
#Skin: Trichoepithelioma  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  Overall Incidence Total 0/150 (0%) Mean 0%  #Skin: Sebaceous Gland: Adenoma  0/50 (0%) 0/50 (0%)  Overall Incidence Total 0/150 (0%)  Overall Incidence Total 0/150 (0%)  Overall Incidence Total 0/150 (0%)  Mean 0%  SD 0%  Total 0/150 (0%)  O/50 (0%)  O	(0%)	,	` ,		` '		Turk	` ,		` ,		(0%)	0/50	•	•	Squamous Cell Papil
Trichoepithelioma           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         Nean 0%         SD (0%)         SD (0%)         Nean 0%         SD (0%)         Nean 0%         SD (0%)         0/50 (0%)	0%	SD 0%	∍an 0%	Mea	(0%)	0/150	l otal	0%	SD	า 0%	Mear	(0%)	)/150	! 	l otal	Overall Incidence
Overall Incidence         Total         0/150 (0%)         Mean 0%         SD 0%         Total         0/150 (0%)         Mean 0%         SD 0%           #Skin: Sebaceous Gland:         Adenoma         0/50 (0%)         0/50	(0%)	0/50 ((	(0%)	0/50	(0%)	0/50		(0%)	0/50	(0%)	0/50	(0%)	0/50			_
#Skin: Sebaceous Gland: Adenoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50  Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%	` '	SD 0%	` ,		` ,		Total	` ,		` '		` ,		I	Total	Overall Incidence
Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0																Skin: Sebaceous Gland
	(0%) 0%	0/50 (C SD 0%	` ,		` '		Total	` ,		` '		` '		I	Total	Overall Incidence
Carcinoma														•••••		Skin: Sebaceous Gland
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50  Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0%	(0%) 0%	0/50 (0 SD 0%	` ,		` ,		Total	` ,		` '		` '		I	Total	Overall Incidence

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (00/)	0/50 (001)	0(10 (00))	•••••	0/50 (00)	0/50 (00/)	0/47 (00)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/47 (0%) SD 0%
*Spleen: Hemangioma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (0%)	0/47 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/47 (0%) SD 0%
*Spleen: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 4/149 (2.68%)	1/50 (2%) Mean 2.69%	2/49 (4%) SD 1.2%	Total	0/50 (0%) 1/147 (0.68%)	1/50 (2%) Mean 0.67%	0/47 (0%) SD 1.15%
*Spleen: Mast Cell Tumor Malignant	t				•••••			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/147 (0%)	0/50 (0%) Mean 0%	0/47 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 90

Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
Spleen: Plasma Cell Tumor Malignan	t							
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/47 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/147 (0.68%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
verali iliciuence	I Olai	0/130 (0/8)	Mean 076	30 0%	ı Olai	0/130 (0/8)	Weall 076	30 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o			0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Forestomach: Squamous Cell Papilloma								
oquamous com rapinoma		2/50 (4%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Stomach, Glandular: Adenoma		0/50 (00/)	0/50 (00)	0/50 (00()		0/50 /00/	0/50 (0%)	0/50 (0%)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male		Female
#Stomach, Glandular: Carcinoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0° Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%) 0/50 (04	%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	,	Mean 0% SD 0%
*Testes: Adenoma		0/50 (00/)	4/52 (00)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0° Mean 0.67% SD 1.15		
Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (04	0/ \	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0° Mean 0% SD 0%	70)	
Thymus: Thymoma Benign		0/45 (00/)		2/47 (20)	2/12 (22)
Overall Incidence	Total	0/45 (0%) 0/127 (0%)	0/44 (0%) 0/38 (0° Mean 0% SD 0%	,	0/46 (0%) 0/43 (0%) Mean 0% SD 0%
*Thymus: Thymoma Malignant		0/45 (09/)	0/44 (00/) 0/22 (0	0/\ 0/47 /00/\	0/46 (09/) 0/42 (09/)
Overall Incidence	Total	0/45 (0%) 0/127 (0%)	0/44 (0%) 0/38 (0° Mean 0% SD 0%	%) 0/47 (0%)  Total 0/136 (0%)	0/46 (0%) 0/43 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma: Benign, Malignan	nt, NOS	0/45 (00/)	0/44 /09/	0/29 (00/)		0/47 (00/)	0/46 (09/)	0/42 (00/)
Overall Incidence	Total	0/45 (0%) 0/127 (0%)	0/44 (0%) Mean 0%	0/38 (0%) SD 0%	Total	0/47 (0%) 0/136 (0%)	0/46 (0%) Mean 0%	0/43 (0%) SD 0%
*Thyroid Gland: Adenoma		0/50 (00/)	0/40 (00/)	0/50 (0%)	•••••	0/50 (00()	0/50 (0%)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
*Thyroid Gland: C-Cell: Carcinoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/146 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/46 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma								
Overall Incidence	Total	0/50 (0%) 4/149 (2.68%)	1/49 (2%) Mean 2.68%	3/50 (6%) SD 3.05%	Total	1/50 (2%) 2/146 (1.37%)	0/50 (0%) Mean 1.39%	1/46 (2%) SD 1.21%
*Thyroid Gland: Follicular Cell: Carcinoma		0/50 (00/)		0/50 (00/)	•••••	4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/49 (2%) Mean 0.68%	0/50 (0%) SD 1.18%	Total	1/50 (2%) 1/146 (0.68%)	0/50 (0%) Mean 0.67%	0/46 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male	Female
*Thyroid Gland: Follicular Cell Carcinoma or Adenoma	:	0/50 (0%)	2/49 (4%) 3/50 (6%)	2/50 (4%) 0/50 (0%) 1/46 (2%)
Overall Incidence	Total	5/149 (3.36%)	Mean 3.36% SD 3.06%	Total 3/146 (2.05%) Mean 2.06% SD 2%
#Tissue NOS: Carcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
#Tissue NOS: Plasma Cell Tumor Maligna	ant	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
#Tissue NOS: Schwannoma Malignant		0/50 (09/)	0/50 /09/\ 0/50 /09/\	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Tongue: Fibroma		0/50 (00/)	4/50 (00)	0/50 /00/) 0/50 /00/) 0/50 /00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 /00/)	0/50 (0%)		0/50 /00/)	0/50 /00/	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Tongue:								
Squamous Cell Carcinoma	or Papillon		0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Institutes	T-4-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma			2/52 (221)			2/22 (221)	(00)	2/52 (224)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma								
3		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/145 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (09/)	0/50 (0%)	4/49 /20/)		0/50 (/0%)	0/50 (09/)	0/45 (09/)
Overell Incidence	T-4-1	0/50 (0%)	0/50 (0%)	1/48 (2%)	Tatal	0/50 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.69%	SD 1.2%	Total	0/145 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

# Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

			Male				Female	
*Urinary Bladder: Plasma Cell Tumor Mali	ignant	0/50 (00/)	0/50 (09/)	0/49 (09/)		0/50 (00/)	1/50 /20/	0/45 (00/)
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 1/145 (0.69%)	1/50 (2%) Mean 0.67%	0/45 (0%) SD 1.15%
*Urinary Bladder: Sarcoma		0/50 (00/)	0/50 (00()	0/40 (00/)		0/50 (00()	0/50 (00()	0/45 (00/)
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/145 (0%)	0/50 (0%) Mean 0%	0/45 (0%) SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma		•••••	•••••	•••••				
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma					•••••			
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Page: 96

Report Date:04/29/2009

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

	Male			Female	
#Uterus: Leiomyoma			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Uterus: Leiomyosarcoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal Overall Incidence		Total	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall incidence		Total	3/150 (2%)	Mean 2%	SD 2%
#Uterus: Sarcoma Stromal			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		••••••	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence		Total	3/150 (2%)	Mean 2%	SD 2%
#Uterus: Schwannoma Malignant			0/50 /00/	0/50 (00/)	0/50 (09/)
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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			Male				Female	
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence					Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Vagina:				•••••				
Squamous Cell Papilloma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

# Page: 98

Report Date:04/29/2009

#### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/04/01 02/10/04 08/09/01	728 730 728	50 (1) 50 (1) 50 (1)	39(698) 32(691) 40(702)	52.9 51.1 52.3	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 052000506 059501106	10/03/01 02/09/04 08/08/01	727 729 727	50 (5) 50 (5) 50 (5)	38(692) 38(711) 39(694)	64.7 63.9 64.4	Formamide Ginseng 5-(Hydroxymethyl)-2-furfural

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 99

Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#All Organs: Benign Tumors		31/50 (62%)	38/50 (76%)	42/50 (84%)		17/50 (34%)	33/50 (66%)	26/50 (52%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 11.14%	Total	76/150 (50.67%)	Mean 50.67%	SD 16.04%
#All Organs: Malignant Tumors		20/50 (50%)	26/50 /520/\	26/50 (520)		26/50 /520/\	4E/E0 (20%)	46/50 (220/)
Overall Incidence	Total	28/50 (56%) 80/150 (53.33%)	26/50 (52%) Mean 53.33%	26/50 (52%) SD 2.31%	Total	26/50 (52%) 57/150 (38%)	15/50 (30%) Mean 38%	16/50 (32%) SD 12.17%
#All Organs: Malignant and Benign To	umors	44/50 (939/)	46/50 (020/)	40/50 (099/)		26/50 /720//	42/50 (040/)	24/50 (699/)
Overall Incidence	Total	41/50 (82%) 136/150 (90.67%)	46/50 (92%) Mean 90.67%	49/50 (98%) SD 8.08%	Total	36/50 (72%) 112/150 (74.67%)	42/50 (84%) Mean 74.67%	34/50 (68%) SD 8.33%
#All Organs: Hemangioma		2/50 (4%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
#All Organs: Hemangiosarcoma		3/50 (6%)	4/50 (8%)	2/50 (4%)		2/50 (4%)	0/50 (0%)	5/50 (10%)
Overall Incidence	Total	9/150 (6%)	Mean 6%	SD 2%	Total	7/150 (4.67%)	Mean 4.67%	SD 5.03%
#All Organs: Hemangiosarcoma or He	emangioma	E/50 (40%)	E/50 (400V)	0/50 (40/)	•••••	0/50 (400)	4/50 (00()	7/50 (440)
Overall Incidence	Total	5/50 (10%) 12/150 (8%)	5/50 (10%) Mean 8%	2/50 (4%) SD 3.46%	Total	2/50 (4%) 10/150 (6.67%)	1/50 (2%) Mean 6.67%	7/50 (14%) SD 6.43%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male				Female	
All Organs: Histiocytic Sarcoma				2/52 (221)		2/20 (40)	2/72 (224)	2/20 (201)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	stiocytic, Lyr	nphocytic, Mixed, NOS						
verall Incidence	Total	2/50 (4%) 8/150 (5.33%)	4/50 (8%) Mean 5.33%	2/50 (4%) SD 2.31%	Total	10/50 (20%) 27/150 (18%)	9/50 (18%) Mean 18%	8/50 (16%) SD 2%
All Organs: Mesothelioma: Benign, M	lalignant, NO	S 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Mesothelioma: Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Osteosarcoma		- (a)	0/20 (00)	(201)			(004)	(20)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 101

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#All Organs: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
*Adrenal Cortex: Adenoma		2/50 /40/\	4/50 (201)	0/40 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	2/50 (4%) 8/149 (5.37%)	1/50 (2%) 5/49 (10%) Mean 5.4% SD 4.28%	0/49 (0%) 0/50 (0%) 0/50 (0%) Total 0/149 (0%) Mean 0% SD 0%
*Adrenal Cortex: Plasma Cell Tumor Malignant		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/149 (0%) Mean 0% SD 0%
*Adrenal Cortex: Sarcoma		0/50 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	Total 0/149 (0%) Mean 0% SD 0%
*Adrenal Medulla: Pheochromocytoma Benign				
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 1/50 (2%) 0/50 (0%)  Total 1/150 (0.67%) Mean 0.67% SD 1.15%
*Adrenal Medulla: Pheochromocytoma Complex		0/50 (00/)	0/50 (00) 0/40 (00)	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Adrenal Medulla: Pheochromocytoma Malig	jnant	1/50 (2%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma: Beni	ign, Complex	κ, <b>Malignant, NOS</b> 1/50 (2%)	0/50 (0%)	0/49 (0%)	•••••	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Bone Marrow: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Malign	nant	0/50 (09/)	0/50 (09/)	0/50 (00/)		0/50 (00/)	0/50 (09/)	0/40 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
#Bone: Hemangiosarcoma		0/50 (00)	(00)	(201)		2/22 (22)	(70)	2(72 (22))
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Page: 103 Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Bone: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (0%)	0/50 (00/)	0/50 (00()		0/50 (00/)	0/50 (0%)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteoma		0/50 /00()	0/50 (00/)	0/50 (00()	•••••	0/50 /00/	0/50 (00/)	0/50 (00())
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/50 (00/)	0/50 /09/	0/50 (00/)		0/50 (/0//)	0/50 (09/.)	0/50 (/0//)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Meningioma Malignant					••••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma						2/22 (221)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Clitoral/Preputial Gland: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
Clitoral/Preputial Gland: Hemangiosarcoma								
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 /00/
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
verali incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	wean 0%	SD 0%
Esophagus: Squamous Cell Carcinoma								- 1
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Eye: Sarcoma		(201)	2/22 (22)	(00)		- ()	(201)	(004)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		6/50 (12%)	11/50 (22%)	11/50 (22%)		4/50 (8%)	7/50 (14%)	7/50 (14%)
verall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 5.77%	Total	18/150 (12%)	Mean 12%	SD 3.46%
Harderian Gland: Carcinoma		0/50 //0/	4/50 (00)	0/50 (00/)		4/50 (00/)	0/50 (00)	0(50 (00))
		2/50 (4%)	1/50 (2%)	3/50 (6%)		4/50 (8%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	6/150 (4%)	Mean 4%	SD 2%	Total	4/150 (2.67%)	Mean 2.67%	SD 4.62%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 106

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma								
Overall Incidence	Total	7/50 (14%) 32/150 (21.33%)	12/50 (24%) Mean 21.33%	13/50 (26%) SD 6.43%	Total	8/50 (16%) 22/150 (14.67%)	7/50 (14%) Mean 14.67%	7/50 (14%) SD 1.15%
#Harderian Gland: Sarcoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Heart: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Hemangiosarcoma		0/50 (00()	4/50 (00()	0/50 (0%)		0/50 (00()	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Heart: Sarcoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Large: Cecum: Carcinoma	•••••	0/50 (004)	0/50 (00/)	4/50 (004)	•••••	0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 107 Report Date:04/29/2009

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

			Male		Female
#Intestine Large: Cecum: Carcinoma or Adenoma					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) 1/50 (2%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
	·····		Wear 0.07% 3D 1.13%		Wear 076 3D 076
#Intestine Large: Cecum: Leiomyoma					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Overall includince		0/130 (0/0)	Wear 070 GB 070	10(2)	Medit 070 GB 070
#Intestine Large: Colon/Rectun Leiomyosarcoma	n:				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
		0/130 (0/0)	Wear 070 GD 070	10(2)	Medit 070 GB 070
#Intestine Small: Duodenum: Adenoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Intestine Small: Duodenum: Carcinoma		(201)		2(22)	
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Overall includince		2/130 (1.33/0)	Wedi 1.35% GD 2.31%	10(2)	Medit 070 GB 070
#Intestine Small: Duodenum: Leiomyosarcoma					
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall incluence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma		0/50 (0%)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
#Intestine Small: Jejunum: Hemangiosarcoma		0/50 /00/)	0/50 (00())	0/50 (00/) 0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (00/)	0/50 (00())	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous		0/50 (00/)	0/50 (09() 0/50 (09()	0/50 (09/) 0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif Adenoma	ied:	0/50 (00/)	0/50 (09/) 0/50 (09/)	0/60 (09/) 0/60 (09/) 0/60 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif				
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
#Intestine Small: Site Unspecif Carcinoma or Adenoma	ied:			
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) 2/50 (4%) Mean 1.33% SD 2.31%	0/50 (0%)     0/50 (0%)     0/50 (0%)       Total     0/150 (0%)     Mean 0%     SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 110

			Male				Female	
Intestine Small: Site Unspecif Hemangiosarcoma	fied:							
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspecific								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspecit Polyp Adenomatous								
1 Olyp Additionations		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Adenoma								
	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
slets, Pancreatic: Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
*Kidney: Renal Tubule: Adenoma				
	<b>.</b>	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Carcinoma		(201)		
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
Overall incidence	Total	1/150 (0.67%)	Mean 0.07% SD 1.15%	Total 0/150 (0%) Weath 0% SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00/)	4/50 (00)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) 1/50 (2%) Mean 1.33% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	Total	2/130 (1.33/0)	Weat 1.55% 3D 1.15%	10tal 0/130 (0/6) Weath 0/6 3D 0/6
*Kidney: Renal Tubule: Hemangioma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0.170 (001)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
Overall incluence	IUIAI	0/100 (0%)	IVICALI U% SD U%	Total 0/130 (0%) Wealt 0% 3D 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna	ant	•••••		
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Liver: Cholangiocarcinoma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Liver: **Fibrous Histiocytoma** 0/50 (0%)(0%)0/50 0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% \*Liver: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Liver: Hemangiosarcoma (2%)(4%)(2%)(0%)0/50 (0%)1/50 2/50 1/50 0/50 **Overall Incidence** Total 4/150 (2.67%) Mean 2.67% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% Hepatoblastoma 1/50 (2%)1/50 (2%)1/50 (2%)0/50 (0%)1/50 (2%)**Overall Incidence** Total 3/150 (2%) Mean 2% SD 0% Total 1/150 (0.67%)Mean 0.67% SD 1.15% \*Liver: Hepatocellular Adenoma 24/50 (48%)(68%)33/50 (66%)6/50 (12%)21/50 (42%)14/50 (28%)**Overall Incidence** SD 15.01% Total 91/150 (60.67%) Mean 60.67% SD 11.02% Total 41/150 (27.33%) Mean 27.33%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Vehicle: WATER

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Species: MICE Strain: B6C3F1 nor Incidence for Selected Control Animal (

Route: GAVAGE

Report Date: 04/29/2009

			Male				Female	
*Liver: Hepatocellular Carcinoma		15/50 (30%)	14/50 (28%)	11/50 (22%)		4/50 (8%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	40/150 (26.67%)	Mean 26.67%	SD 4.16%	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%
*Liver: Hepatocellular Carcinoma	or Hepatobl	astoma						
Overall Incidence	Total	16/50 (32%) 42/150 (28%)	14/50 (28%) Mean 28%	12/50 (24%) SD 4%	Total	4/50 (8%) 9/150 (6%)	2/50 (4%) Mean 6%	3/50 (6%) SD 2%
*Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma 33/50 (66%)	39/50 (78%)	39/50 (78%)		9/50 (18%)	23/50 (46%)	14/50 (28%)
Overall Incidence	Total	111/150 (74%)	Mean 74%	SD 6.93%	Total	46/150 (30.67%)	Mean 30.67%	SD 14.19%
*Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocelli							
Overall Incidence	Total	34/50 (68%) 112/150 (74.67%)	39/50 (78%) Mean 74.67%	39/50 (78%) SD 5.77%	Total	9/50 (18%) 47/150 (31.33%)	23/50 (46%) Mean 31.33%	15/50 (30%) SD 14.05%
*Liver: Hepatocholangiocarcinoma	a	4/50 (20()	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Liver: Hepatocholangioma		0/50 (09/)	0/50 (0%)	0/50 (09/)		0/50 (09/)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Ito Cell Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Aden	noma	40/50 (000)	0/50 /400/	40/50 (00%)		4/50 (00()	0/50 /400/	0/50 (40/)
Overall Incidence	Total	10/50 (20%) 29/150 (19.33%)	9/50 (18%) Mean 19.33%	10/50 (20%) SD 1.15%	Total	4/50 (8%) 12/150 (8%)	6/50 (12%) Mean 8%	2/50 (4%) SD 4%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups **Route:** GAVAGE

Vehicle: WATER

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Report Date:04/29/2009

Contract/Lab: All Laboratories Species: MICE

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Ca	arcinoma							
		6/50 (12%)	3/50 (6%)	7/50 (14%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	16/150 (10.67%)	Mean 10.67%	SD 4.16%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
ung: Alveolar/Bronchiolar Ca Adenoma	arcinoma or Al	veolar/Bronchiolar						
		16/50 (32%)	12/50 (24%)	16/50 (32%)		5/50 (10%)	7/50 (14%)	3/50 (6%)
verall Incidence	Total	44/150 (29.33%)	Mean 29.33%	SD 4.62%	Total	15/150 (10%)	Mean 10%	SD 4%
ung: Fibrosarcoma verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
ung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
ung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
ung: Plasma Cell Tumor Mali	gnant							
		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00//

0/50 (0%)

SD 0%

0/50

0/150 (0%)

Total

(0%)

0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Total

0/50

0/150 (0%)

(0%)

(0%)

Mean 0%

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Route: GAVAGE

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups

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Contract/Lab: All Laboratories

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
*Lung: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangioma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node: Plasma Cell Tumor Maligr	nant				•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node: Sarcoma					•••••	(00)		0/20 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

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al Groups Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICE

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma								
r ibrous riistiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant					•••••			
Mast Cen Tumor Mangham		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Malignant	:							
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Overall illuluellue	ı Ulai	0/100 (0%)	IVICALI U70	3D 0%	i Ulai	0/100 (070)	IVICALI U%	3D 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 118

			Male				Female	
Lymph Node, Mesenteric: Hemangioma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								4/50 (00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Lymph Node, Mesenteric:								
Plasma Cell Tumor Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Adenoacanthoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
//ammary Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for S

Tumor Incidence for Selected Control Animal Groups

Page: 119

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
#Mammary Gland: Fibroadenoma					•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenoma	or Adenoma							
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mammary Gland: Fibroma, Fibroadenoma	, Carcinoma, o							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%
Mesentery: Fibrosarcoma				•••••			•••••	•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Mesentery: Hemangioma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

### 111 also All Laboratoria

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 120

			Male				Female	
Mesentery: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma		0.700		2(-2 (22)		- ()	(00)	0.750 (001)
huanall luaidan aa	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Nose:								
Mast Cell Tumor Malig	nant	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous o		nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Squamous Cell Carcin	, Tongue, Phary	nx, Tooth, Gingiva):						
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma	, Tongue, Phary	Squamous, or						
		0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%		Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 121

	Male		Female
*Ovary: Choriocarcinoma		0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	al 0/150 (0%)	Mean 0% SD 0%
*Ovary: Cystadenoma			
Overall Incidence	Tota	1/50 (2%) al 11/150 (7.33%)	7/50 (14%) 3/50 (6%) Mean 7.33% SD 6.11%
*Ovary: Fibrous Histiocytoma			
Overall Incidence	Tota	0/50 (0%) al 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Tota	` '	Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor Malignant		0/50 (0%)	
Overall Incidence	Tota	` ,	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/20 (00)	
Overall Incidence	Tota	0/50 (0%) al 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 122

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

	Male		Female	
*Ovary: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%
*Ovary: Leiomyosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Luteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%
*Ovary: Plasma Cell Tumor Malignant		2/52 (201)		
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Ovary: Teratoma Benign		0/50 (004)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 123

Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Mean 0% SD 0%  %) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%  %) 0/50 (0%) 0/49 (0%) Mean 0% SD 0%  %) 0/50 (0%) 0/49 (0%) Mean 0% SD 0%	
*Ovary: Teratoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	` '	` '
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	` '	( ,
*Pancreas: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	` '	( ,
*Pancreas: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (09/)	0/40 /09/)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/148 (0%)		` ,
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/49 (0%) 0/148 (0%)	` ,	` ,
*Pituitary Gland: Pars Distalis	or Unspecif	ied Site:						
Overall Incidence	Total	1/50 (2%) 2/148 (1.35%)	1/50 (2%) Mean 1.33%	0/48 (0%) SD 1.15%	Total	3/50 (6%) 6/149 (4.03%)	1/50 (2%) Mean 4.03%	2/49 (4%) SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

trol Animal Groups

Page: 124

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:						
		1/50 (2%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/148 (0.68%)	Mean 0.67%	SD 1.15%	Total	0/149 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma				•••••		•••••		
		2/50 (4%)	1/50 (2%)	0/48 (0%)		3/50 (6%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	3/148 (2.03%)	Mean 2%	SD 2%	Total	6/149 (4.03%)	Mean 4.03%	SD 2%
*Pituitary Gland: Pars Interme Adenoma	edia:							
		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%
*Pituitary Gland: Pars Interme Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)		1/50 (2%)	1/50 (2%)	2/49 (4%)
Overall Incidence	Total	0/30 (0 %)	Mean 0%	SD 0%	Total	4/149 (2.68%)	Mean 2.69%	SD 1.2%
*Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma				•••••	•••••	•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

### . May 2000

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 125

			Male			Female  0/49 (0%) 0/50 (0%) 0/49 (0%)  Total 0/148 (0%) Mean 0% SD 0%  Total 0/148 (0%) 0/50 (0%) 0/49 (0%)  Total 0/148 (0%) Mean 0% SD 0%  Total 0/148 (0%) 0/50 (0%) 0/49 (0%)  Total 0/148 (0%) Mean 0% SD 0%		
*Prostate: Hemangioma		0(50 (00))	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/40 (0%)	0/50 (0%)	0/40 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	` '	` '	` ,
*Salivary Glands: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	` ,
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/40 (00/)	0/50 (09/)	0/40 (09/)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	` '	` ,	` ,
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
#Skeletal Muscle: Fibrosarcoma		0/50 /00()	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00()	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

## Contract/Lab: All Laboratories

**Toxicology Data Management System**Tumor Incidence for Selected Control Animal Groups

Page: 126 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Skeletal Muscle: Myxosarcoma		0/50 (00)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyom		0/50 (00/)			0/50 (00)	0/50 (00/)	0/50 (00)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
keletal Muscle: Sarcoma	•••••							
overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma or Ba	sosquamou		0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incid

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 127

			Male			Female		
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous <sup>-</sup>	Tumor Benign, or						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin:		•••••				•••••		
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma ( NOS)		ous Tumor (malignant o						
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma, Tumor (benign, malign	ant or NOS), or	Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)	Tara	0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	Total  noma, Carcinon oma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq	` '	` '	Total	` ,	` ,	` '
Basal Cell Carcinoma, Tumor (benign, malign overall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend	Total  noma, Carcinon oma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma	Mean 0%	SD 0% ′	Total  Total	0/150 (0%) <sup>′</sup>	Mean 0%	SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan everall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´	Mean 0%	SD 0% / / / / / / / / / / / / / / / / / /
Basal Cell Carcinoma, Tumor (benign, malign verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan	noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / O/50 (0%) SD 0%		0/150 (0%) ´  0/50 (0%)  0/50 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% 0/50 (0%) SD 0%
Basal Cell Carcinoma, Tumor (benign, malign everall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan everall Incidence	noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% / O/50 (0%)	SD 0% /		0/150 (0%) ´	Mean 0%	SD 0% / / / / / / / / / / / / / / / / / /

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System** Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 128

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skin: Fibroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, o	r					
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%
#Skin: Fibrosarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	3/50 (6%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 3.46%
#Skin: Fibrosarcoma, Sarcoma Histiocytoma		a, or Fibrous						0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	1/50 (2%) 5/150 (3.33%)	4/50 (8%) Mean 3.33%	0/50 (0%) SD 4.16%
#Skin: Fibrous Histiocytoma		0/50 (00()	0/50 /00/	0/50 (00/)		0/50 (0%)	4/50 (20()	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
#Skin: Granular Cell Tumor Ber	nign	0/50 (00()	0/50 (00/)	0/50 (00)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# Contract/Lab: All Laboratories

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups Page: 129

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

			Male				Female	
Skin: Hemangioma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Liposarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Myxosarcoma	••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Neurofibrosarcoma or S		malignant or NOS) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Skin: Neurofibrosarcoma, Net malignant or NOS)	urofibroma, or	, ,						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 130

			Male				Female	
Skin: Osteosarcoma								
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sarcoma		0/50 (00/)	0/50 (00/)	0/50 (001)		4/50 (00)	0/50 (00/)	0/50 (00)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
Skin: Schwannoma Malignant	•••••	0/50 (0%)	1/50 (2%)	0/50 (0%)	•••••	0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	2/50 (4%) Mean 1.33%	0/50 (0%) SD 2.31%
Skin: Squamous Cell Carcinon	na							
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcinor Basosquamous Tumor (ı			0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillom	a	0/50 (00()	0/50 /09/	0/50 (00/)		0/50 (00/.)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
Skin: Squamous Cell Papillo	ma or Papillom							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillo Carcinoma or Keratoac		-						
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Papillo verall Incidence		or Keratoacanthoma 0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
kin: Trichoepithelioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma		0/50 (00/.)	0/50 (00()	0/50 (00/)		0/50 (0%)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Sebaceous Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	` ,	` ,	0/50 (0%) SD 0%	Total	` '	` ,	0/50 (0%) SD 0%
verali incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 132

			Male				Female	
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Meningioma Malignant		0/50 (00/)	0/50 (00/)	0/50 (00/)		0(50 (004)	0/50 (004)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Spleen: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma		0/50 (00/)	0/50 (00/)	0/50 (001)		0(50 (004)	4/50 (00)	0/40 (00/)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
Spleen: Hemangiosarcoma								
-		2/50 (4%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	4/49 (8%)
verall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	5/149 (3.36%)	Mean 3.39%	SD 4.25%
Spleen: Mast Cell Tumor Malignant			(00)	(00)			(00)	(20)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 133

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Spleen: Plasma Cell Tumor Malignan	t							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (00/)	0/50 (0%)	0/50 /00/)		0/50 /00/)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incidence	TOTAL	0/150 (0%)	wean 0%	SD 0%	ı olal	0/150 (0%)	wean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma				- 1 1				
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma o			1/50 (2%)	2/50 (4%)	•••••	1/50 (2%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	2/30 (4%) SD 2%	Total	3/150 (2%)	Mean 2%	2/30 (4 <i>%</i> ) SD 2%
verali iliciuelice	TOtal	3/130 (2/6)	Weall 270	3D 2/6	ı Olai	3/130 (2/6)	ivicaii 270	3D 270
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
Stomach, Glandular: Adenoma		0/50 /00/	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 134

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male		Female	
#Stomach, Glandular: Carcinoma						
Occupation of the second	T-1-1	0/50 (0%)	0/50 (0%) 0/50	` ,	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0% SE	D 0% Total	0/150 (0%) Mean 0% SD 0%	
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (00/)	0/50 (09/) 0/50	(00()	0/50 (09/) 0/50 (09/) 0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0% Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/150 (0%) Mean 0% SD 0%	
					0,100 (0,0)	
*Testes: Adenoma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0%		
		` ,				
*Testes: Hemangiosarcoma						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 Mean 0% SE	(0%) D 0%		
Overall includince	Total	0/130 (070)	WCarr 070 CL			
*Thymus: Thymoma Benign						
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) 0/43 Mean 0% SE	(0%) D 0% Total	0/49 (0%) 0/48 (0%) 0/47 (0%) 0/144 (0%) Mean 0% SD 0%	
Overali ilicidence	ı Ulai	0/13/ (070)	iviedii U% SL	7 0 /0 10tal	0/144 (0/0) Wealt 0% 5D 0%	
*Thymus: Thymoma Malignant		0.117 (001)	0/47 (00/)	(001)	0/40 (001)	
Overall Incidence	Total	0/47 (0%) 0/137 (0%)	0/47 (0%) 0/43 Mean 0% SE	(0%) D 0% Total	0/49 (0%) 0/48 (0%) 0/47 (0%) 0/144 (0%) Mean 0% SD 0%	
Overall incluence	IUlai	U/13/ (U70)	iviean 0% SL	0 0 /0 TOTAL	0/144 (0/0) Weatt 0/0 SD 0/0	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 135

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Thymus: Thymoma: Benign, Malignar	nt, NOS	0/47 (0%)	0/47 (0%)	0/43 (0%)		0/49 (0%)	0/48 (0%)	0/47 (0%)
Overall Incidence	Total	0/137 (0%)	Mean 0%	SD 0%	Total	0/144 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%)	1/50 (2%)	2/50 (4%)		2/49 (4%)	0/49 (0%)	1/48 (2%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/146 (2.05%)	Mean 2.05%	SD 2.04%
*Thyroid Gland: Follicular Cell: Carcinoma		4/50 (00)	0/50 (00/)	0/50 (00)		0/40 (00/)	0/40 (00/)	0/40 (004)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/49 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/48 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
ouroma or Auditoma		1/50 (2%)	1/50 (2%)	2/50 (4%)		2/49 (4%)	0/49 (0%)	1/48 (2%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 1.15%	Total	3/146 (2.05%)	Mean 2.05%	SD 2.04%
Tissue NOS: Carcinoma		0/50 (00/)	0/50 (00)	0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Tissue NOS: Hemangiosarcoma		2/22 (22/)	2/22 (22/)	. (201)		2/22 (224)	(201)	2/22 (224)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Plasma Cell Tumor Malignant								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
<b>3</b>		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Tongue: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 137

Report Date:04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
#Tongue: Squamous Cell Carcinom	ıa	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Tongue: Squamous Cell Carcinom	na or Papillon		0/50 (00/)	0/50 (00/)	•••••	0/50 (00/)	0/50 (00/)	4/50 (00()
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Tongue: Squamous Cell Papilloma	a	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma		(IE) (O)()	0/50 (00)	0/50 (00)		0/50 /00/	2/42 (22/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (00)	0/50 (00)		0/50 /00/	0/40 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Urinary Bladder: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)(0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% ..... \*Urinary Bladder: Sarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/149 Mean 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% #Uterus: Hemangioma 0/50 (0%)(0%)2/50 (4%)**Overall Incidence** Total 2/150 (1.33%) Mean 1.33% SD 2.31% **#Uterus:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories
Species: MICF

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: WATER

	Male		Female	
#Uterus: Leiomyoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tot	al 0/150 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma		0/50 (0%)		
Overall Incidence	Tot	` '	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal				
Overall Incidence	Tot	0/50 (0%) al 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Sarcoma Stromal				
Overall Incidence	Tot	` ,	Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal				
Overall Incidence	Tot	0/50 (0%) al 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Schwannoma Malignant				
Overall Incidence	Tot	0/50 (0%) al 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma				•••••				(201)
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Zymbal's Gland: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:04/29/2009

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	052001106 059601106 059901706 059700602 058800604 059700806 059302506	07/21/03 06/11/01 08/18/03 06/05/00 07/30/01 09/17/01 06/23/03	729 729 729 729 729 729 729	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	37(689) 38(709) 31(686) 40(709) 35(698) 37(694) 36(695)	53.4 53.9 53.8 53.2 54.9 53.5 52.9	1-Bromopropane Cumene Diethylamine Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin
				Fer	nale		
Battelle Northwest	052001106 059601106 059901706 059700602 058800604 059700806 059302506	07/21/03 06/11/01 08/18/03 06/05/00 07/30/01 09/17/01 06/23/03	731 731 731 731 731 731 731	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	36(698) 37(685) 32(684) 35(695) 39(701) 39(699) 31(663)	61.2 60.7 60.7 60.3 58.6 58.3 62.1	1-Bromopropane Cumene Diethylamine Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Tetralin

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#All Organs: Benign Tumors								
•		36/50 (72%) 27/50 (54%) 42/50 (84%)	43/50 (86%) 35/50 (70%)	33/50 (66%) 28/50 (56%)		22/50 (44%) 29/50 (58%) 24/50 (48%)	34/50 (68%) 26/50 (52%)	25/50 (50%) 26/50 (52%)
Overall Incidence	Total	244/350 (69.71%)	Mean 69.71%	SD 12.41%	Total	186/350 (53.14%)	Mean 53.14%	SD 7.82%
#All Organs: Malignant Tumors								
ū		30/50 (60%) 29/50 (58%) 26/50 (52%)	27/50 (54%) 19/50 (38%)	36/50 (72%) 22/50 (44%)		33/50 (66%) 30/50 (60%) 27/50 (54%)	26/50 (52%) 29/50 (58%)	23/50 (46%) 23/50 (46%)
Overall Incidence	Total	189/350 (54%)	Mean 54%	SD 11.08%	Total	191/350 (54.57%)	Mean 54.57%	SD 7.37%
#All Organs: Malignant and Benign Tu					•••••			
		47/50 (94%) 45/50 (90%) 47/50 (94%)	48/50 (96%) 43/50 (86%)	48/50 (96%) 38/50 (76%)		42/50 (84%) 42/50 (84%) 40/50 (80%)	42/50 (84%) 40/50 (80%)	41/50 (82%) 37/50 (74%)
Overall Incidence	Total	316/350 (90.29%)	Mean 90.29%	SD 7.25%	Total	284/350 (81.14%)	Mean 81.14%	SD 3.63%
#All Organs: Hemangioma					•••••			
·		0/50 (0%) 1/50 (2%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: INHALATION Vehicle: AIR

			Male				Female	
All Organs: Hemangiosarcoma								
-		2/50 (4%)	0/50 (0%)	7/50 (14%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		3/50 (6%)	4/50 (8%)	2/50 (4%)		3/50 (6%)	4/50 (8%)	2/50 (4%)
		4/50 (8%)				2/50 (4%)		
verall Incidence	Total	22/350 (6.29%)	Mean 6.29%	SD 4.39%	Total	21/350 (6%)	Mean 6%	SD 2.83%
II Organs:				•••••		•••••		
Hemangiosarcoma or H	emangioma							
		2/50 (4%)	1/50 (2%)	7/50 (14%)		4/50 (8%)	1/50 (2%)	5/50 (10%)
		4/50 (8%)	4/50 (8%)	2/50 (4%)		3/50 (6%)	5/50 (10%)	2/50 (4%)
		5/50 (10%)				2/50 (4%)		
rerall Incidence	Total	25/350 (7.14%)	Mean 7.14%	SD 4.14%	Total	22/350 (6.29%)	Mean 6.29%	SD 3.15%
All Organs:								
Histiocytic Sarcoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
		0/50 (0%)	0/30 (0/0)	1750 (270)		2/50 (4%)	1750 (270)	1730 (270)
verall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%	Total	9/350 (2.57%)	Mean 2.57%	SD 1.9%
 All Organs:						•••••		
Malignant Lymphoma: I or Undifferentiated Cell		nphocytic, Mixed, NO	5,					
		2/50 (4%)	2/50 (4%)	2/50 (4%)		17/50 (34%)	7/50 (14%)	8/50 (16%)
		1/50 (2%)	0/50 (0%)	1/50 (2%)		13/50 (26%)	15/50 (30%)	13/50 (26%)
		2/50 (4%)				12/50 (24%)		
verall Incidence	Total	10/350 (2.86%)	Mean 2.86%	SD 1.57%	Total	85/350 (24.29%)	Mean 24.29%	SD 7.16%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 144 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male **Female** #All Organs: Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)(0.29%)SD 0.76% SD 0% Overall Incidence Total 1/350 Mean 0.29% Total 0/350 (0%) Mean 0% #All Organs: Mesothelioma: Malignant 0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)(0%)(0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/350 (0.29%) Mean 0.29% SD 0.76% Total 0/350 (0%) Mean 0% SD 0% #All Organs: Osteoma 0/50 (0%)(0%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total 0/350 (0%) Mean 0% Total 0/350 (0%) Mean 0% #All Organs: Osteosarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 1/50 (2%)0/50 0/50 (0%)0/50 (0%)(0%)(0%) 0/50 0/50 **Overall Incidence** Total 2/350 (0.57%) Mean 0.57% SD 0.98% Total 0/350 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female
#All Organs: Osteosarcoma or Osteoma				
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/350 (0.57%)	Mean 0.57% SD 0.98%	Total 0/350 (0%) Mean 0% SD 0%
*Adrenal Cortex: Adenoma	• • • • • • • • • • • • • • • • • • • •			
		4/49 (8%) 2/50 (4%) 2/49 (4%)	1/50 (2%) 6/50 (12%) 0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	16/347 (4.61%)	Mean 4.61% SD 4.13%	Total 2/349 (0.57%) Mean 0.57% SD 0.98%
*Adrenal Cortex: Plasma Cell Tumor Malignar	 nt			
-		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0% SD 0%	Total 0/349 (0%) Mean 0% SD 0%
*Adrenal Cortex: Sarcoma				
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0% SD 0%	Total 0/349 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Adrenal Medulla: Pheochromocytoma Beni	ign							
		1/50 (2%) 0/50 (0%) 1/47 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)		3/50 (6%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%) 1/48 (2%)
Overall Incidence	Total	2/344 (0.58%)	Mean 0.59%	SD 1.01%	Total	8/348 (2.3%)	Mean 2.3%	SD 2.43%
Adrenal Medulla: Pheochromocytoma Com	nplex							
	•	0/50 (0%) 0/50 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)
Overall Incidence	Total	0/344 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma Mali	gnant							
,		0/50 (0%) 1/50 (2%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)
Overall Incidence	Total	1/344 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%
Adrenal Medulla:	ian Comple	v Malianant NOS						
Pheochromocytoma: Ben	iigii, Comple	1/50 (2%) 1/50 (2%) 1/50 (2%) 1/47 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/47 (0%)		4/50 (8%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 2/50 (4%)	0/50 (0%) 1/48 (2%)
Overall Incidence	Total	3/344 (0.87%)	Mean 0.88%	SD 1.09%	Total	9/348 (2.59%)	Mean 2.58%	SD 2.99%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Bone Marrow: Hemangioma								
		0/48 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma								
v		0/48 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%)	1/50 (2%) 2/50 (4%)
Overall Incidence	Total	2/348 (0.57%)	Mean 0.57%	SD 1.51%	Total	4/349 (1.15%)	Mean 1.14%	SD 1.57%
*Bone Marrow: Plasma Cell Tumor Malig								
-		0/48 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
#Bone: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Bone: Osteoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
<sup>∤</sup> Bone: Osteosarcoma					•••••			
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteon					•••••			
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	Total	0/350 (0%)	Mean 0%	SD 0%
Bone: Sarcoma					•••••			
		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Meningioma: Benign, Mal								
<b>G</b> ,	,	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant								
· ·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Adenoma								
		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/46 (0%) 0/45 (0%) 0/46 (0%)	0/41 (0%) 0/43 (0%)	0/46 (0%) 0/42 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/309 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma					•••••			
		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/46 (0%) 0/45 (0%) 0/46 (0%)	0/41 (0%) 0/43 (0%)	0/46 (0%) 0/42 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/309 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma					•••••			
		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/46 (0%) 0/45 (0%) 0/46 (0%)	0/41 (0%) 0/43 (0%)	0/46 (0%) 0/42 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/309 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangioma					•••••			
J		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/46 (0%) 0/45 (0%) 0/46 (0%)	0/41 (0%) 0/43 (0%)	0/46 (0%) 0/42 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/309 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Hemangiosarcoma								
_		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/45 (0%) 0/46 (0%)	0/43 (0%)	0/42 (0%)
overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/309 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma			•••••					
•		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/46 (0%)	0/41 (0%)	0/46 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/45 (0%) 0/46 (0%)	1/43 (2%)	0/42 (0%)
verall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/309 (0.32%)	Mean 0.33%	SD 0.88%
Esophagus: Squamous Cell Carcinoma			•••••				•••••	
·		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Eye: Sarcoma			•••••				•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)		SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION
Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Harderian Gland: Adenoma 7/50 (14%)8/50 (16%)4/50 (8%)3/50 (6%)8/50 (16%)3/50 (6%)(10%)6/50 5/50 10/50 (20%)3/50 (6%)(12%)3/50 (6%)4/50 (8%)2/50 (4%)1/50 (2%)SD 5.76% SD 4.62% Overall Incidence Total 39/350 (11.14%) Mean 11.14% Total 28/350 (8%) Mean 8% #Harderian Gland: Carcinoma 3/50 (6%)4/50 (8%)4/50 (8%)2/50 (4%)5/50 (10%)2/50 (4%)2/50 (4%)(2%)(2%)1/50 (0%)1/50 3/50 (6%)1/50 (2%)0/50 3/50 (6%)1/50 (2%) SD 3.21% **Overall Incidence** Total 20/350 (5.71%) Mean 5.71% SD 2.14% Total 12/350 (3.43%) Mean 3.43% #Harderian Gland: Carcinoma or Adenoma (20%)10/50 11/50 (22%)8/50 (16%)5/50 (10%)12/50 (24%)5/50 (10%)7/50 (14%)11/50 (22%)6/50 (12%)7/50 (14%)4/50 (8%) 4/50 (8%) 5/50 (10%)2/50 (4%) Overall Incidence Total 58/350 (16.57%) Mean 16.57% SD 4.86% Total 39/350 (11.14%) Mean 11.14% SD 6.41% #Harderian Gland: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% 

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Route: INHALATION

Vehicle: AIR

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			Male				Female	
Heart: Hemangioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma					•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
Heart: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Leiomyoma								••••••
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
fintestine Large: Colon/Rectur Leiomyosarcoma					•••••			
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
fIntestine Small: Duodenum: Adenoma					•••••			
		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: AIR

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Small: Duodenum: Leiomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Intestine Small: Duodenum: Polyp Adenomatous								
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Carcinoma					•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
fIntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fintestine Small: Ileum: Polyp Adenomatous					•••••			
,		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Intestine Small: Jejunum: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Carcinoma					•••••			
		4/50 (8%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	8/350 (2.29%)	Mean 2.29%	SD 2.93%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyosarcoma	•••••				•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous	•••••				•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Unspeci Adenoma	fied:				•••••			
		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Intestine Small: Site Unspection	ecified:							
		4/50 (8%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	8/350 (2.29%)	Mean 2.29%	SD 2.93%	Total	0/350 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspection Carcinoma or Adenoma			•••••					
		4/50 (8%) 1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	9/350 (2.57%)	Mean 2.57%	SD 2.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Intestine Small: Site Unsp Hemangiosarcoma	ecified:							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspo								
,		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male	Female
fIntestine Small: Site Unspecif Polyp Adenomatous	fied:			
		1/50 (2%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29% SD 0.76%	Total 1/350 (0.29%) Mean 0.29% SD 0.76%
Islets, Pancreatic: Adenoma				
		0/48 (0%) 1/49 (2%) 2/49 (4%)	0/50 (0%) 2/50 (4%) 0/50 (0%) 1/49 (2%)	0/50 (0%) 1/49 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/345 (1.74%)	Mean 1.74% SD 1.82%	Total 1/348 (0.29%) Mean 0.29% SD 0.77%
slets, Pancreatic: Carcinoma				
		0/48 (0%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/345 (0.29%)	Mean 0.29% SD 0.76%	Total 1/348 (0.29%) Mean 0.29% SD 0.76%
Islets, Pancreatic: Carcinoma or Adenoma				
		0/48 (0%) 1/49 (2%) 2/49 (4%)	0/50 (0%) 2/50 (4%) 1/50 (2%) 1/49 (2%)	0/50 (0%) 1/49 (2%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	7/345 (2.03%)	Mean 2.02% SD 1.65%	Total 2/348 (0.57%) Mean 0.58% SD 0.99%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma							•••••	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma				•••••			•••••	
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

N	flale	Female
0/49 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)	(0%) 0/50 (0%) (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
al 0/347 (0%) Mea	n 0% SD 0%	Total 0/349 (0%) Mean 0% SD 0%
0/49 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)	(0%) 0/50 (0%) (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
al 0/347 (0%) Mea	n 0% SD 0%	Total 0/349 (0%) Mean 0% SD 0%
0/50 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)	(0%) 0/50 (0%) (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
al 0/348 (0%) Mea	n 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0%
0/50 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)	(0%) 0/50 (0%) (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
al 0/348 (0%) Mea	n 0% SD 0%	Total 0/350 (0%) Mean 0% SD 0%
al	0/49 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)  I 0/347 (0%) Mea  0/49 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)  I 0/347 (0%) Mea  0/50 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)  I 0/348 (0%) Mea  0/50 (0%) 0/50 0/49 (0%)  0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/50 (0%) 0/50 0/49 (0%)	0/50 (0%) 0/49 (0%) 0/49 (0%)  I 0/347 (0%) Mean 0% SD 0%  0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) I 0/347 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) I 0/348 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Liver: Hemangioma								
•		0/50 (0%) 1/50 (2%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/348 (0.57%)	Mean 0.57%	SD 0.98%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
*Liver: Hemangiosarcoma				•••••			•••••	
-		1/50 (2%) 2/50 (4%) 1/49 (2%)	0/50 (0%) 4/50 (8%)	2/50 (4%) 1/49 (2%)		0/50 (0%) 1/50 (2%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	11/348 (3.16%)	Mean 3.15%	SD 2.54%	Total	5/350 (1.43%)	Mean 1.43%	SD 1.51%
*Liver: Hepatoblastoma					••••••			
		1/50 (2%) 0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/49 (0%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/348 (0.86%)	Mean 0.86%	SD 1.07%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
*Liver: Hepatocellular Adenoma				•••••				
		30/50 (60%) 17/50 (34%) 33/49 (67%)	34/50 (68%) 24/50 (48%)	28/50 (56%) 21/49 (43%)		19/50 (38%) 13/50 (26%) 14/50 (28%)	18/50 (36%) 10/50 (20%)	14/50 (28%) 15/50 (30%)
Overall Incidence	Total	187/348 (53.74%)	Mean 53.74%	SD 12.74%	Total	103/350 (29.43%)	Mean 29.43%	SD 6.08%
					• • • • • • • • • • • • • • • • • • • •			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

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Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

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Report Date:04/29/2009

Vehicle: AIR

Length of Study: CHRONIC

				M	ale						Fema	ale		
*Liver:														
Hepatocellular Carcine	oma	15/50	(30%)	13/50	(26%)	20/50	(40%)		5/50	(10%)	10/50	(20%)	4/50	(8%)
		12/50	(24%)	10/50	(20%)		(20%)		6/50	(12%)	3/50	(6%)	4/50	(8%)
		11/49	(22%)	. 0, 00	(=070)	. 5, . 5	(=070)		7/50	(14%)	0,00	(0,0)	., 00	(373)
Overall Incidence	Total	91/348	(26.15%)	Mear	26.12%	SD 7.	02%	Total	39/350	(11.14%)	Mea	n 11.14%	SD	4.74%
*Liver:	•••••			•••••			•••••					•••••		•••••
Hepatocellular Carcine	oma or Hepatobl	astoma												
		16/50	(32%)	14/50	(28%)		(40%)		5/50	(10%)	10/50	(20%)	4/50	(8%)
		12/50	(24%)	10/50	(20%)	10/49	(20%)		6/50	(12%)	3/50	(6%)	4/50	(8%)
O	T-1-1	11/49	(22%)		00.000/	00.7	000/	Taral	7/50	(14%)		- 44 4 40/	0.0	4.740/
Overall Incidence	Total	93/348 (	(26.72%)	iviear	1 26.69%	SD 7.	26%	Total	39/350	(11.14%)	ivieai	n 11.14%	20	4.74%
*Liver:														
Hepatocellular Carcine	oma or Hepatoce													
		38/50	(76%)	40/50	(80%)		(80%)		24/50	(48%)	25/50	(50%)	16/50	(32%)
		27/50	(54%)	28/50	(56%)	26/49	(53%)		17/50	(34%)	13/50	(26%)	17/50	(34%)
	<b>-</b>	37/49	(76%)		07.00/	00.46	700/	<b>-</b>	20/50	(40%)		07.740/	0.0	0.750/
Overall Incidence	Total	236/348	(67.82%)	Mear	67.8%	SD 12	2.72%	Total	132/350	(37.71%)	Mea	n 37.71%	SD	8.75%
***************************************														
*Liver:														
Hepatocellular Carcine	oma, Hepatocelli	ular Adenom	na, or											
	oma, Hepatocell	ular Adenom 38/50	na, or (76%)	41/50	(82%)	40/50	(80%)		24/50	(48%)	25/50	(50%)	16/50	(32%)
Hepatocellular Carcine	oma, Hepatocell		·	41/50 28/50	(82%) (56%)		(80%) (53%)		24/50 17/50	(48%) (34%)	25/50 13/50	(50%) (26%)	16/50 17/50	(32%) (34%)
	oma, Hepatocell	38/50	(76%)		` '		` '			` '		` '		` ,

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Liver: Hepatocholangiocarcinoma								
		1/50 (2%) 5/50 (10%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/348 (1.72%)	Mean 1.71%	SD 3.73%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Liver: Hepatocholangioma	•••••							
		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Benign								
		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignant								•••••
·		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/348 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System** Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Length of Study: CHRONIC

Male **Female** \*Liver: **Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 0/49 (0%)0/50 0/50 0/49 (0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/348 (0%) Mean 0% Total 0/350 (0%) Mean 0% \*Liver: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/49 **Overall Incidence** Total 0/348 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% ..... \*Lung: Adenoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) SD 0% **Overall Incidence** Total 1/350 (0.29%) Mean 0.29% SD 0.76% Total 0/350 (0%) Mean 0% Alveolar/Bronchiolar Adenoma 6/50 (12%)13/50 (26%)4/50 (8%)1/50 (2%)1/50 2/50 (4%)(8%) 9/50 (18%)(16%)10/50 (20%)4/50 1/50 (2%)3/50 (6%)10/50 (20%)6/50 (12%)**Overall Incidence** Total 60/350 (17.14%) Mean 17.14% SD 5.87% Total 18/350 (5.14%) Mean 5.14% SD 3.8% 

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

**Female** Male \*Lung: Alveolar/Bronchiolar Carcinoma 8/50 (16%)9/50 (18%)12/50 (24%)0/50 (0%)3/50 (6%)3/50 (6%)(10%)(0%)5/50 5/50 (10%)(14%)0/50 1/50 (2%)2/50 (4%)11/50 (22%)0/50 (0%)57/350 (16.29%) SD 2.76% Overall Incidence Total Mean 16.29% SD 5.47% Total 9/350 (2.57%) Mean 2.57% Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 15/50 (8%)5/50 (10%)13/50 (26%)19/50 (38%)(30%)1/50 (2%)4/50 14/50 (28%)(26%)(34%)4/50 (8%) 2/50 (4%)5/50 (10%)13/50 17/50 20/50 (40%)6/50 (12%)Overall Incidence Total 111/350 (31.71%) Mean 31.71% SD 5.71% Total 27/350 (7.71%)Mean 7.71% SD 3.55% \*Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% \*Lung: Fibrous Histiocytoma (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 (0%) (0%)0/50 (0%)0/50 0/50 0/50 (0%) 0/50 (0%)0/50 **Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 167

			Male				Female	
*Lung: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
*Lung: Plasma Cell Tumor Maligr	nant							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma			•••••	•••••				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma	• • • • • • • • • • • • • • • • • • • •							
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
		0/50 (0%)	0/30 (0/0)	0/30 (0/0)		0/50 (0%)	0/30 (0/0)	0/30 (0/0)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node: Hemangiosarcoma							•••••	
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node: Plasma Cell Tumor Malig								
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/350 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Lymph Node, Mandibular: Fibrous Histiocytoma				•••••			•••••	•••••
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Hemangiosarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant	•••••							
Š		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 170 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male				Female	
#Lymph Node, Mandibular: Plasma Cell Tumor Malignar	nt							
-		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma	•••••				•••••			
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 171 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female	
#Lymph Node, Mesenteric: Plasma Cell Tumor Malig	nant					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)		50 (0%) 50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 0/350 (0%)		SD 0%
#Mammary Gland: Adenoacanthoma	•••••					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	` ,	50 (0%) 50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma						
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	` ,	50 (0%) 50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%
Mammary Gland:	•••••					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%) 1/50 (2%)	` ,	50 (8%) 50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 10/350 (2.86%)	Mean 2.86%	SD 2.54%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		2/50 (4%) 1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	4/50 (8%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	10/350 (2.86%)	Mean 2.86%	SD 2.54%
#Mammary Gland: Fibroadenoma				•••••				•••••
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Mammary Gland: Fibroma, Fibroadenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Mammary Gland:			•••••	•••••			•••••	•••••
Fibroma, Fibroadenoma,	Carcinoma, o	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		2/50 (4%) 1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	5/50 (10%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	11/350 (3.14%)	Mean 3.14%	SD 3.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Mesentery: Hemangioma	•••••							
J		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		1/50 (2%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)
verall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	4/350 (1.14%)	Mean 1.14%	SD 1.57%
Mesentery: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Nose: Mast Cell Tumor Malig	ınant							
		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa Papilloma Squamous	, Tongue, Phary	nx, Tooth, Gingiva):						
	·	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Oral Cavity (Oral Mucosa		nx, Tooth, Gingiva):						
Squamous Cell Carcin		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	Total	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
·	Total	0/50 (0%)	` ,		Total	0/50 (0%)		
Overall Incidence	Total ,	0/50 (0%) 0/50 (0%) 1/350 (0.29%) 	0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence  #Oral Cavity (Oral Mucosa Squamous Cell Carcin	Total ,	0/50 (0%) 0/50 (0%) 1/350 (0.29%) 	0/50 (0%)	0/50 (0%)	Total	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: INHALATION Vehicle: AIR

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Male				Fema	ale		
*Ovary: Choriocarcinoma							
		0/50 0/49 0/50	(0%) (0%) (0%)	0/48 0/48	(0%) (0%)	0/49 0/49	(0%) (0%)
Overall Incidence	Total	0/343	` ,	Mear	n 0%	SD	0%
			•••••				
'Ovary: Cystadenoma							
oystadonoma —		3/50 0/49 2/50	(6%) (0%) (4%)	5/48 2/48	(10%) (4%)	3/49 6/49	(6%) (12%)
Overall Incidence	Total	21/343	(6.12%)	Mear	6.14%	SD	4.12%
Ovary:							
Fibrous Histiocytoma		0/50 0/49 0/50	(0%) (0%) (0%)	0/48 0/48	(0%) (0%)	0/49 0/49	(0%) (0%)
Overall Incidence	Total	0/343	` ,	Mear	n 0%	SD	0%
Ovary: Granulosa Cell Tumor Benign							
		0/50 0/49 0/50	(0%) (0%) (0%)	0/48 0/48	(0%) (0%)	0/49 0/49	(0%) (0%)
Overall Incidence	Total		(0%)	Mear	n 0%	SD	0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date:04/29/2009

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	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant				
		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/343 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/343 (0%)	Mean 0%	SD 0%
*Ovary:				
Hemangioma		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/343 (0%)	Mean 0%	SD 0%
*Ovary:				
Hemangiosarcoma		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	1/49 (2%) 0/49 (0%)
Overall Incidence	Total	1/343 (0.29%)	Mean 0.29%	SD 0.77%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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M	ale		Female	
Ovary: Leiomyosarcoma				
		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 1/49 (2%)
Overall Incidence	Total	1/343 (0.29%)	Mean 0.29%	SD 0.77%
Ovary: Luteoma				
		1/50 (2%) 0/49 (0%) 1/50 (2%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	2/343 (0.58%)	Mean 0.57%	SD 0.98%
Ovary: Plasma Cell Tumor Malignant				
· ····································		0/50 (0%) 0/49 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/343 (0%)	Mean 0%	SD 0%
Ovary: Teratoma Benign				
		0/50 (0%) 0/49 (0%) 1/50 (2%)	1/48 (2%) 0/48 (0%)	0/49 (0%) 0/49 (0%)
Overall Incidence	Total	2/343 (0.58%)	Mean 0.58%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:04/29/2009

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

		Male					Female			
*Ovary: Teratoma Malignant										
<b>3</b>						0/50 (0%)	0/48 (0%)	0/49 (0%)		
						0/49 (0%)	0/48 (0%)	0/49 (0%)		
						1/50 (2%)				
Overall Incidence					Total	1/343 (0.29%)	Mean 0.29%	SD 0.76%		
Over					•••••					
Ovary: Tubulostromal Adenoma	•									
rubulostromai Adenoma						0/50 (0%)	0/48 (0%)	0/49 (0%)		
						0/49 (0%)	0/48 (0%)	0/49 (0%)		
						0/50 (0%)				
verall Incidence					Total	0/343 (0%)	Mean 0%	SD 0%		
				•••••	• • • • • • • • • • • • • • • • • • • •			•••••		
Pancreas: Adenoma										
7.440.14		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		
Overall Incidence	Total	0/345 (0%)	Mean 0%	SD 0%	Total	0/348 (0%)	Mean 0%	SD 0%		
Pancreas:		•••••			• • • • • • • • • • • • • • • • • • • •					
Carcinoma										
Oai Cillollia		1/48 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)		
		0/49 (0%)	( ( ) ( )	(-,-)		0/50 (0%)	(-,-)	( ( , , )		
Overall Incidence	Total	1/345 (0.29%)	Mean 0.3%	SD 0.79%	Total	` '	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

I. May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Pancreas: Carcinoma or Adenoma								
		1/48 (2%) 0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	1/345 (0.29%)	Mean 0.3%	SD 0.79%	Total	0/348 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distal Adenoma					•••••			
		1/46 (2%) 0/50 (0%) 0/50 (0%)	1/48 (2%) 0/48 (0%)	0/50 (0%) 0/47 (0%)		5/46 (11%) 7/50 (14%) 6/49 (12%)	8/50 (16%) 4/50 (8%)	10/50 (20%) 4/50 (8%)
Overall Incidence	Total	2/339 (0.59%)	Mean 0.61%	SD 1.04%	Total	44/345 (12.75%)	Mean 12.73%	SD 4.35%
Pituitary Gland: Pars Distal Carcinoma					•••••			
		0/46 (0%) 0/50 (0%) 0/50 (0%)	0/48 (0%) 0/48 (0%)	0/50 (0%) 0/47 (0%)		1/46 (2%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/339 (0%)	Mean 0%	SD 0%	Total	2/345 (0.58%)	Mean 0.6%	SD 1.02%
Pituitary Gland: Pars Distal Carcinoma or Adenoma					•••••			
		1/46 (2%) 0/50 (0%) 0/50 (0%)	1/48 (2%) 0/48 (0%)	0/50 (0%) 0/47 (0%)		6/46 (13%) 7/50 (14%) 6/49 (12%)	8/50 (16%) 4/50 (8%)	10/50 (20%) 5/50 (10%)
Overall Incidence	Total	2/339 (0.59%)	Mean 0.61%	SD 1.04%	Total	46/345 (13.33%)	Mean 13.33%	SD 3.93%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

11. May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female					
*Pituitary Gland: Pars Intermedia: Adenoma												
		0/46 (0%) 0/50 (0%) 0/50 (0%)	0/48 (0%) 1/48 (2%)	0/50 (0%) 0/47 (0%)		0/46 (0%) 0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%)	2/50 (4%) 0/50 (0%)				
Overall Incidence	Total	1/339 (0.29%)	Mean 0.3%	SD 0.79%	Total	5/345 (1.45%)	Mean 1.43%	SD 1.9%				
Pituitary Gland: Pars Intern Carcinoma or Adenoma	media:											
		0/46 (0%) 0/50 (0%) 0/50 (0%)	0/48 (0%) 1/48 (2%)	0/50 (0%) 0/47 (0%)		0/46 (0%) 0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%)	2/50 (4%) 0/50 (0%)				
Overall Incidence	Total	1/339 (0.29%)	Mean 0.3%	SD 0.79%	Total	5/345 (1.45%)	Mean 1.43%	SD 1.9%				
Prostate: Adenoma		•••••					•••••					
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)								
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%								
Prostate: Carcinoma or Adenoma												
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)								
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%								

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Hemangioma								
		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
		0/49 (0%)						
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%
Salivary Glands: Carcinoma or Adenoma								
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%
Salivary Glands: Mast Cell Tumor Malignant	:							
<b>g</b>		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/348 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Length of Study: CHRONIC

Species: MICE Strain: B6C3F1

Route: INHALATION Vehicle: AIR

Tumor Incidence for Selected Control Animal Groups

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			Male				Female	
#Seminal Vesicle: Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%				
Skeletal Muscle: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Hemangiosarcoma								
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Skeletal Muscle: Myxosarcoma			•••••					
-		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skeletal Muscle:			•••••	•••••				
Rhabdomyosarcoma or	Knabdomyom	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:								
Basal Cell Adenoma or	Basosquamou	s Tumor Benign 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Male Female #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% ..... #Skin: **Basal Cell Carcinoma** (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)SD 0% **Overall Incidence** Total 0/350 Mean 0% SD 0% Total 0/350 (0%) Mean 0% Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** Mean 0% SD 0% 0/350 Mean 0% SD 0% Total 0/350 Total Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 Mean 0% SD 0% Total 0/350 Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq. Papilloma, Keratoacanthoma, Trichoepithelioma (0%)0/50 0/50 (0%)0/50 (2%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/350 (0%)Mean 0% SD 0% Total 1/350 (0.29%) Mean 0.29% SD 0.76% #Skin: Basosquamous Tumor Benign 0/50 (0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% #Skin: **Fibroma** 0/50 (0%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%) 0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%)Total Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma (2%)(8%)0/50 (0%)2/50 (4%)1/50 8/50 (16%)0/50 (0%)4/50 (8%) 1/50 (2%)0/50 (0%)0/50 4/50 6/50 (12%)2/50 (4%)(4%)1/50 (2%)2/50 **Overall Incidence** Total 6/350 (1.71%) Mean 1.71% SD 1.8% Total 25/350 (7.14%)Mean 7.14% SD 5.64%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Fibrosarcoma, Sarcoma Histiocytoma								
•		0/50 (0%) 1/50 (2%) 2/50 (4%)	2/50 (4%) 0/50 (0%)	1/50 (2%) 0/50 (0%)		8/50 (16%) 4/50 (8%) 1/50 (2%)	0/50 (0%) 6/50 (12%)	4/50 (8%) 2/50 (4%)
Overall Incidence	Total	6/350 (1.71%)	Mean 1.71%	SD 1.8%	Total	25/350 (7.14%)	Mean 7.14%	SD 5.64%
#Skin: Fibrous Histiocytoma	•••••							
		0/50 (0%) 1/50 (2%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		1/50 (2%) 2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%	Total	3/350 (0.86%)	Mean 0.86%	SD 1.57%
#Skin: Granular Cell Tumor Be	enign					•••••		
	-	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female
#Skin: Hemangioma					
ū		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	,	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29% SD 0.76	` ,	Mean 0% SD 0%
#Skin: Hemangiosarcoma					
-		0/50 (0%) 0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (29) 1/50 (2%) 0/50 (09)		1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	4/350 (1.14%)	Mean 1.14% SD 1.57	% Total 3/350 (0.86%)	Mean 0.86% SD 1.07%
#Skin: Liposarcoma					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (09) 0/50 (0%) 0/50 (09)	,	0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 1/350 (0.29%)	Mean 0.29% SD 0.76%
#Skin: Myxosarcoma					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 0/350 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin:								
Neurofibrosarcoma or Se	chwannoma (r		0.50	2(52 (22)		0.4=0 (00.4)	0/=0 (00/)	2/22 (22/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Institutes	Tatal	` '	Mann 00/	CD 00/	Tatal	` ,	Maa: 00/	CD 00/
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:								
Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	Schwannoma (benign,						
g,		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	, ,	, ,		0/50 (0%)	, ,	, ,
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:				• • • • • • • • • • • • • • • • • • • •				
Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin:								
Sarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		7/50 (14%)	0/50 (0%)	4/50 (8%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	6/50 (12%)	2/50 (4%)
		1/50 (2%)		()		1/50 (2%)	(1-77)	(1,0)
Overall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%	Total	22/350 (6.29%)	Mean 6.29%	SD 5.22%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

i: May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skin:								
Squamous Cell Carcinor	na	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	4/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
		•••••			• • • • • • • • • • • • • • • • • • • •		•••••	• • • • • • • • • • • • • • • • • • • •
#Skin: Squamous Cell Carcinor Basosquamous Tumor (		NOS), or Carcinoma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Squamous Cell Carcinor		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Squamous Cell Carcinor Basosquamous Tumor ( Overall Incidence	malignant or N	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	0/50 (0%) SD 0.76%
Squamous Cell Carcinor Basosquamous Tumor ( Overall Incidence #Skin:	malignant or N	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	0/50 (0%) SD 0.76%
Squamous Cell Carcinor Basosquamous Tumor ( Overall Incidence	malignant or N	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	0/50 (0%) SD 0.76%
Basosquamous Tumor (  Overall Incidence  #Skin:	malignant or N	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/350 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/50 (0%) 1/350 (0.29%)	0/50 (0%) Mean 0.29%	0/50 (0%) SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

: May2009

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Squamous Cell Papillo	oma or Panillom							
Squamous Cell Fapilio	onia or Fapinonia	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/00 (0/0)	0/00 (0/0)		0/50 (0%)	0/00 (0/0)	0/00 (0/0)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Ckin.					•••••			
Squamous Cell Papillo Squamous Cell Papillo Carcinoma or Keratoa		Squamous Cell						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Skin:								
Squamous Cell Papillo	oma, Papilloma,	or Keratoacanthoma						
	•	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Skin: Trichoepithelioma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)				0/50 (0%)		
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
#Skin: Sebaceous Gland: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%
Spinal Cord: Meningioma Malignant								
2		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/346 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Spleen: Hemangioma								
-		0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/346 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
_		2/48 (4%) 1/50 (2%) 1/49 (2%)	0/50 (0%) 1/50 (2%)	3/50 (6%) 1/49 (2%)		1/50 (2%) 1/50 (2%) 1/50 (2%)	0/49 (0%) 0/50 (0%)	2/50 (4%) 1/50 (2%)
Overall Incidence	Total	9/346 (2.6%)	Mean 2.61%	SD 1.92%	Total	6/349 (1.72%)	Mean 1.71%	SD 1.38%
Spleen: Mast Cell Tumor Malignant			•••••					
-		0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/346 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 193

			Male				Female	
Spleen: Plasma Cell Tumor Maligna	ant							
		0/48 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/346 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Mast Cell Tumor Malignant	:							
Ü		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/350 (0.57%)	Mean 0.57%	SD 1.51%	Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%
#Stomach, Forestomach:	or Donillon	Caucamana		•••••				
Squamous Cell Carcinoma	от гаршоп	0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)
Overall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.57%	Total	6/350 (1.71%)	Mean 1.71%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

11. Way2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 194

			Male				Female	
Stomach, Forestomach: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	4/350 (1.14%)	Mean 1.14%	SD 1.07%
#Stomach, Glandular: Adenoma	•••••							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma								
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Testes: Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%				
P1								
Testes: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%				
Thymus: Thymoma Benign					• • • • • • • • • • • • • • • • • • • •			
, ,		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		0/42 (0%) 0/47 (0%)	0/41 (0%)	0/47 (0%)		0/49 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/341 (0%)	Mean 0%	SD 0%
Thymus: Thymoma Malignant	•••••							
5		0/38 (0%)	0/45 (0%)	0/38 (0%)		0/49 (0%)	0/49 (0%)	0/47 (0%)
		1/42 (2%) 0/47 (0%)	0/41 (0%)	0/47 (0%)		0/49 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.9%	Total	0/341 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1 Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thymus: Thymoma: Benign, Malign	ant, NOS							
		0/38 (0%) 1/42 (2%) 0/47 (0%)	0/45 (0%) 0/41 (0%)	0/38 (0%) 0/47 (0%)		0/49 (0%) 0/49 (0%) 0/48 (0%)	0/49 (0%) 0/50 (0%)	0/47 (0%) 0/49 (0%)
Overall Incidence	Total	1/298 (0.34%)	Mean 0.34%	SD 0.9%	Total	0/341 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma								
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	0/349 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma								
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%
Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••							
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/49 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/347 (0%)	Mean 0%	SD 0%	Total	1/349 (0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 197 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: INHALATION Vehicle: AIR

			Male	Female
Thyroid Gland: Follicular Cell: Adenoma				
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 3/50 (6%) 0/49 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 3/50 (6%) 2/50 (4%) 0/50 (0%)
Overall Incidence	Total	3/347 (0.86%)	Mean 0.86% SD 2.27%	Total 6/349 (1.72%) Mean 1.71% SD 2.43%
Thyroid Gland: Follicular Cell: Carcinoma				
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)	0/49 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	0/347 (0%)	Mean 0% SD 0%	Total 3/349 (0.86%) Mean 0.86% SD 1.07%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma				
		0/49 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 3/50 (6%) 0/49 (0%)	0/49 (0%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 3/50 (6%) 2/50 (4%) 1/50 (2%)
Overall Incidence	Total	3/347 (0.86%)	Mean 0.86% SD 2.27%	Total 9/349 (2.58%) Mean 2.57% SD 2.23%
Tissue NOS: Carcinoma	•••••			
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0% SD 0%	Total 1/350 (0.29%) Mean 0.29% SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System** Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

**Route: INHALATION** Vehicle: AIR

Length of Study: CHRONIC

**Female** Male **#Tissue NOS:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)SD 0% SD 0% Overall Incidence Total 0/350 (0%)Mean 0% Total 0/350 (0%) Mean 0% **#Tissue NOS: Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% **#Tissue NOS:** Schwannoma Malignant (0%)(0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%)0/50 (0%) SD 0% SD 0% **Overall Incidence** Total 0/350 (0%) Mean 0% Total 0/350 (0%) Mean 0% #Tongue: **Fibroma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/350 (0%) Mean 0% SD 0% Total 0/350 (0%) Mean 0% SD 0% 

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female				
#Tongue: Squamous Cell Carcinoma										
		0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	0/350 (0%)	Mean 0%	SD 0%		
Tongue:										
Squamous Cell Carcinoma	or Papillom	na Squamous 0/50 (0%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		
verall Incidence	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%		
Tongue: Squamous Cell Papilloma					•••••					
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)		
verall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total	1/350 (0.29%)	Mean 0.29%	SD 0.76%		
Tooth: Odontoma					•••••					
		0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	3/350 (0.86%)	Mean 0.86%	SD 1.57%	Total	0/350 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female				
Urinary Bladder: Hemangioma										
		0/47 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/345 (0%)	Mean 0%	SD 0%	Total	0/346 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Hemangiosarcoma	•••••									
·		0/47 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		1/50 (2%) 0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		
overall Incidence	Total	0/345 (0%)	Mean 0%	SD 0%	Total	1/346 (0.29%)	Mean 0.29%	SD 0.76%		
Urinary Bladder: Plasma Cell Tumor Malig										
		0/47 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/345 (0%)	Mean 0%	SD 0%	Total	0/346 (0%)	Mean 0%	SD 0%		
Urinary Bladder: Sarcoma										
		0/47 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)		0/50 (0%) 0/50 (0%) 0/49 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/345 (0%)	Mean 0%	SD 0%	Total	0/346 (0%)	Mean 0%	SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 201

	Male		Female				
#Uterus: Adenoma							
			0/50 (0%) 0/50 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		
Overall Incidence		Total	2/350 (0.57%)	Mean 0.57%	SD 0.98%		
#Uterus: Carcinoma							
Garsinoma			0/50 (0%) 1/50 (2%) 1/50 (2%)	3/50 (6%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence		Total	5/350 (1.43%)	Mean 1.43%	SD 2.23%		
Uterus:							
Hemangioma			0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		
Overall Incidence		Total	0/350 (0%)	Mean 0%	SD 0%		
#Uterus: Hemangiosarcoma							
Hemangiosarooma			0/50 (0%) 1/50 (2%) 1/50 (2%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)		
Overall Incidence		Total	3/350 (0.86%)	Mean 0.86%	SD 1.07%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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	Male				Female	
#Uterus: Leiomyoma						
			0/50 0/50 0/50	(0%) (0%) (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total	1/350	(0.29%)	Mean 0.29%	SD 0.76%
#Uterus: Leiomyosarcoma						
			0/50 0/50 1/50	(0%) (0%) (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)
Overall Incidence		Total	2/350	(0.57%)	Mean 0.57%	SD 0.98%
#Uterus:						
Polyp Stromal			0/50 3/50 1/50	(0%) (6%) (2%)	3/50 (6%) 3/50 (6%)	1/50 (2%) 2/50 (4%)
Overall Incidence		Total		(3.71%)	Mean 3.71%	SD 2.43%
#Uterus: Sarcoma Stromal						
53.55 53. <b>53</b>			0/50 1/50 0/50	(0%) (2%) (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence		Total		(0.29%)	Mean 0.29%	SD 0.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Female	
	0/50 (0%) 4/50 (8%) 1/50 (2%)	3/50 (6%) 3/50 (6%)	1/50 (2%) 2/50 (4%)
Total	14/350 (4%)	Mean 4%	SD 2.83%
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	0/350 (0%)	Mean 0%	SD 0%
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	0/350 (0%)	Mean 0%	SD 0%
	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Total	0/350 (0%)		SD 0%
	Total Total	4/50 (8%) 1/50 (2%) 1/50 (2%) Total 14/350 (4%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%) 4/50 (8%) 3/50 (6%) 1/50 (2%)  Total 14/350 (4%) Mean 4%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0%   Total 0/350 (0%) 0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date:04/29/2009

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			Male			Female	
#Zymbal's Gland: Carcinoma							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma							
		0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/350 (0%)	Mean 0%	SD 0%	Total 0/350 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 205

Report Date:04/29/2009

# **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902704 050517406 059900706 059201306 052000804	07/29/02 N/A 05/12/03 02/03/00 03/25/03	729 N/A 729 729 729	50 (1) 0 (0) 50 (1) 50 (1) 50 (1)	46(715) 0(0) 43(715) 45(717) 45(712)	50.0 N/A 48.3 46.1 49.8	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract
				Fer	nale		
Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute Southern Research Institute	059902704 050517406 059900706 059201306 052000804	07/29/02 08/20/02 05/12/03 02/03/00 03/25/03	732 728 732 734 732	50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	45(698) 41(696) 44(718) 42(706) 40(714)	50.3 51.8 51.9 45.6 51.0	Chromium picolinate monohydrate Cresols Goldenseal root powder 4-Methylimidazole Milk thistle extract

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 206

			Male				Female	
All Organs: Benign Tumors								
benign runors		28/50 (56%)		28/50 (56%)		16/50 (32%)	16/50 (32%)	17/50 (34%)
		26/50 (52%)	21/50 (42%)			18/50 (36%)	18/50 (36%)	(5175)
verall Incidence	Total	103/200 (51.5%)	Mean 51.5%	SD 6.61%	Total	85/250 (34%)	Mean 34%	SD 2%
All Organs: Malignant Tumors								
_		24/50 (48%)	20/50 (500/)	20/50 (40%)		22/50 (44%)	20/50 (40%)	13/50 (26%)
Nevall Incidence	Total	15/50 (30%)	29/50 (58%)	CD 44 000/	Total	20/50 (40%)	19/50 (38%)	CD 6 040/
Overall Incidence	Total	88/200 (44%)	Mean 44%	SD 11.89%	Total	94/250 (37.6%)	Mean 37.6%	SD 6.84%
#All Organs: Malignant and Benign T	umors							
		40/50 (80%) 34/50 (68%)	39/50 (78%)	38/50 (76%)		31/50 (62%) 29/50 (58%)	29/50 (58%) 32/50 (64%)	26/50 (52%)
Overall Incidence	Total	151/200 (75.5%)	Mean 75.5%	SD 5.26%	Total	147/250 (58.8%)	Mean 58.8%	SD 4.6%
All Organs: Hemangioma						•••••		•••••
Hemangioma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	2/50 (4%)	, ,		0/50 (0%)	1/50 (2%)	, ,
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#All Organs: Hemangiosarcoma								
		2/50 (4%) 1/50 (2%)	3/50 (69/.)	2/50 (4%)		3/50 (6%)	1/50 (2%) 2/50 (4%)	1/50 (2%)
		1/30 (2%)	3/50 (6%)			3/50 (6%)	∠/3U (4%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
All Organs:	Jomangioma							
Hemangiosarcoma or H	nemangioma	2/50 (4%)		2/50 (4%)		3/50 (6%)	1/50 (2%)	1/50 (2%)
		1/50 (2%)	4/50 (8%)	, ,		3/50 (6%)	3/50 (6%)	,
verall Incidence	Total	9/200 (4.5%)	Mean 4.5%	SD 2.52%	Total	11/250 (4.4%)	Mean 4.4%	SD 2.19%
All Organs: Histiocytic Sarcoma			•••••					
riistiocytic Sarconia		0/50 (0%)		0/50 (0%)		1/50 (2%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		1/50 (2%)	1/50 (2%)	, ,
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	5/250 (2%)	Mean 2%	SD 1.41%
or Undifferentiated Cell	Total	2/50 (4%) 3/50 (6%) 12/200 (6%)	6/50 (12%) Mean 6%	1/50 (2%) SD 4.32%	Total	5/50 (10%) 7/50 (14%) 36/250 (14.4%)	7/50 (14%) 11/50 (22%) Mean 14.4%	6/50 (12%) SD 4.56%
All Organs:								
	Malignant NO	3						
Mesothelioma: Benign,	Malignant, NO	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Mesothelioma: Benign,	-	0/50 (0%) 0/50 (0%)	0/50 (0%)	,		0/50 (0%)	0/50 (0%)	,
Mesothelioma: Benign,	Malignant, NO	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total			0/50 (0%) SD 0%
Mesothelioma: Benign, verall Incidence	Total	0/50 (0%) 0/50 (0%)	` ,	,	Total	0/50 (0%)	0/50 (0%)	,
Mesothelioma: Benign,	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	` ,	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Mesothelioma: Benign, everall Incidence All Organs:	Total	0/50 (0%) 0/50 (0%)	` ,	,	Total	0/50 (0%)	0/50 (0%)	,

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#All Organs: Osteosarcoma or Oste								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
*Adrenal Cortex: Adenoma				•••••		•••••		
		0/50 (0%) 4/50 (8%)	1/50 (2%)	2/50 (4%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	7/200 (3.5%)	Mean 3.5%	SD 3.42%	Total	0/249 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Mal								
	-	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups Δι Page: 209

Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Adrenal Cortex: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma B	enign					•••••	•••••	
		0/49 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/247 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma C	omplex							
·	•	0/49 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma M	alignant							
•	•	0/49 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	1/49 (2%) 0/49 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	3/247 (1.21%)	Mean 1.22%	SD 1.11%
Adrenal Medulla:				•••••		•••••	•••••	
Pheochromocytoma: E	Benign, Complex	x, Malignant, NOS 0/49 (0%) 0/50 (0%)	1/49 (2%)	0/50 (0%)		1/49 (2%) 1/50 (2%)	1/49 (2%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%	Total	3/247 (1.21%)	Mean 1.22%	SD 1.11%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 210

			Male				Female	
Bone Marrow: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Bone Marrow: Hemangiosarcoma					•••••			
		0/50 (0%) 1/50 (2%)	1/49 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/249 (0%)	Mean 0%	SD 0%
Bone Marrow: Plasma Cell Tumor Malig	ınant					•••••		
		0/50 (0%) 0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%
Bone:						•••••		
Hemangiosarcoma		0/50 (0%)	2/22 (22/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		` ,				` ,		
Bone: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 211

			Male				Female	
#Bone: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Bone: Osteosarcoma or Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Bone: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain:	•••••		••••••	•••••				•••••
Meningioma Benign		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
<b>3 3</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 212

			Male				Female	
*Brain: Meningioma: Benign, Mali	gnant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Brain: Schwannoma Malignant	••••••	0/50 (0%)		0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma		0/50 (0%)		0/50 (0%)	•••••	0/44 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/240 (0%)	0/47 (0%) Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma	•••••	0/50 (0%)		0/50 (0%)		0/44 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/240 (0.42%)	0/47 (0%) Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (0%)		0/50 (0%)	•••••	0/44 (0%)	1/49 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%	Total	0/44 (0/8) 0/50 (0%) 1/240 (0.42%)	0/47 (0%) Mean 0.41%	SD 0.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Page: 213 Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Clitoral/Preputial Gland: Hemangioma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%) 0/50 (0%)	0/49 (0%) 0/47 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/240 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma					•••••	•••••	•••••	•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%) 0/50 (0%)	0/49 (0%) 0/47 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/240 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/44 (0%) 0/50 (0%)	0/49 (0%) 0/47 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/240 (0%)	Mean 0%	SD 0%
Esophagus: Squamous Cell Carcinoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Eye: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Harderian Gland: Adenoma 5/50 (10%)(14%)7/50 (14%)(12%)(10%)(8%) 4/50 5/50 (10%)6/50 (12%)6/50 (12%)SD 1.41% **Overall Incidence** Total 21/200 (10.5%) SD 2.52% 30/250 (12%) Mean 12% Mean 10.5% Total #Harderian Gland: Carcinoma 1/50 (2%)2/50 (4%)1/50 (4%)1/50 (2%)0/50 (0%)1/50 (2%)2/50 (4%) **Overall Incidence** Total Mean 2% SD 1.63% 8/250 (3.2%) Mean 3.2% SD 1.1% 4/200 (2%) Total #Harderian Gland: Carcinoma or Adenoma 5/50 (10%)(18%)(18%)7/50 (14%)(14%)5/50 (10%)(10%)7/50 (14%) 8/50 (16%)**Overall Incidence** Total 24/200 (12%) Mean 12% SD 4% Total 38/250 (15.2%)Mean 15.2% SD 1.79% #Harderian Gland: Sarcoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/200 (0%) Mean 0% Total 0/250 (0%) Mean 0% \*Heart: Hemangioma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 0/250 (0%)Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: FEED

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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I Groups Report Date: 04/29/2009

Nopo.

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

			Male		Female				
Heart: Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
leart: Sarcoma		(201)		(004)		2/72 (201)	0.50	(201)	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
ntestine Large: Cecum: Carcinoma			•••••						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
ntestine Large: Cecum: Carcinoma or Adenoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
ntestine Large: Cecum: Leiomyoma									
•		0/50 (0%)	2/22 (224)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%	
veran incluence	TULAI	0/200 (0%)	IVICALI U70	3D 0%	i Ulai	0/200 (0%)	IVICALI U70	3D 0%	

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Coute: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

	·		Male				Female	
#Intestine Large: Colon/Rectur	m:							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma	•••••					•••••		
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Leiomyosarcoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous								
··		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

 n
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 Groups
 Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

			Male				Female	
Intestine Small: Ileum: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Carcinoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Animal Groups Report Date:04/29/2009

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Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Intestine Small: Jejunum: Polyp Adenomatous								
. 77		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecifie Adenoma						•••••		
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecifie			•••••			•••••		
		2/50 (4%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.31%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Intestine Small: Site Unsp Carcinoma or Adenom								
		3/50 (6%) 0/50 (0%)	0/50 (0%)	2/50 (4%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	5/200 (2.5%)	Mean 2.5%	SD 3%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Site Unsp Hemangiosarcoma	pecified:	•••••						
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unsp Leiomyosarcoma								
,		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Site Unsp Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Islets, Pancreatic: Adenoma	•••••				•••••			
		1/50 (2%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	1/48 (2%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	Total	2/246 (0.81%)	Mean 0.82%	SD 1.12%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Page: 220

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		2/50 (4%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	2/246 (0.81%)	Mean 0.8%	SD 1.79%
slets, Pancreatic: Carcinoma or Adenoma								
		1/50 (2%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		2/50 (4%) 0/49 (0%)	1/50 (2%) 0/49 (0%)	1/48 (2%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.5%	SD 1%	Total	4/246 (1.63%)	Mean 1.62%	SD 1.68%
Kidney: Renal Tubule: Adenoma	•••••							
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/249 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma						•••••		
Carcinoma		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/249 (0%)	Mean 0%	SD 0%
						•••••		•••••
Ca. Chiana di Addinina		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 3%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) tal 0/249 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) tal 0/249 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
*Kidney: Renal Tubule: Hemangioma		0/50 (0%)	0/50 (00/)	0/50 (0%)				0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/249 (0%)	` '	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma		0/50 (0%)		0/50 (0%)			0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/249 (0%)	0/50 (0%)	(,
*Kidney: Renal Tubule: Plasma Cell Tumor Maligi		0/50 (0%)		0/50 (0%)			0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/50 (0%)	(,
*Liver: Cholangiocarcinoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Fibrous Histiocytoma								0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 222

			Male				Female	
Liver: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hemangiosarcoma								
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hepatoblastoma								•••••
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Hepatocellular Adenoma	•••••							
,		21/50 (42%) 17/50 (34%)	12/50 (24%)	22/50 (44%)		1/50 (2%) 4/50 (8%)	4/50 (8%) 3/50 (6%)	3/50 (6%)
Overall Incidence	Total	72/200 (36%)	Mean 36%	SD 9.09%	Total	15/250 (6%)	Mean 6%	SD 2.45%
Liver: Hepatocellular Carcinoma					•••••			
		15/50 (30%) 10/50 (20%)	17/50 (34%)	8/50 (16%)		3/50 (6%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	3/50 (6%)
Overall Incidence	Total	50/200 (25%)	Mean 25%	SD 8.41%	Total	8/250 (3.2%)	Mean 3.2%	SD 2.68%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System** Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** \*Liver: Hepatocellular Carcinoma or Hepatoblastoma 15/50 (30%)(18%)3/50 (6%)1/50 (2%)3/50 (6%)(20%)(0%)10/50 17/50 (34%)1/50 (2%)0/50 **Overall Incidence** 51/200 (25.5%) Mean 25.5% SD 7.72% Total 8/250 (3.2%) Mean 3.2% SD 2.68% Total \*Liver: Hepatocellular Carcinoma or Hepatocellular Adenoma 32/50 (64%)(52%)4/50 (8%)4/50 (8%)(12%)23/50 (46%)26/50 (52%)5/50 (10%)3/50 (6%)**Overall Incidence** Mean 53.5% SD 7.55% 22/250 (8.8%)Mean 8.8% SD 2.28% Total 107/200 (53.5%) Total \*Liver: Hepatocellular Carcinoma, Hepatocellular Adenoma, or Hepatoblastoma (64%)26/50 (52%)4/50 (8%)4/50 (8%)6/50 (12%)(46%)26/50 23/50 (52%)5/50 (10%)3/50 (6%)**Overall Incidence** Total 107/200 (53.5%) Mean 53.5% 22/250 (8.8%)Mean 8.8% SD 2.28% SD 7.55% Total \*Liver: Hepatocholangiocarcinoma 0/50 (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)Overall Incidence Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/250 (0%) Mean 0% SD 0% \*Liver: Hepatocholangioma 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Liver: Ito Cell Tumor Benign								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Plasma Cell Tumor Maligr								
Ū		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
iver:			•••••					
Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Adenoma			•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Lung: Alveolar/Bronchiolar Adenoma 13/50 (26%)(8%)1/50 (2%)5/50 (10%)(8%)(0%)8/50 (16%)1/50 (2%)0/50 1/50 (2%)26/200 (13%) **Overall Incidence** Total Mean 13% SD 10.39% Total 11/250 (4.4%) Mean 4.4% SD 4.34% \*Lung: Alveolar/Bronchiolar Carcinoma 3/50 (6%)(12%)1/50 (2%)2/50 (4%)1/50 (2%)2/50 (4%)10/50 (20%)3/50 (6%) 1/50 (2%) **Overall Incidence** Total Mean 10.5% SD 7.19% 8/250 (3.2%) Mean 3.2% SD 1.79% 21/200 (10.5%) Total \*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma (32%)10/50 (20%)2/50 (4%)5/50 (10%)5/50 (10%)(6%) 9/50 (18%)11/50 (22%)3/50 2/50 (4%)**Overall Incidence** Total 46/200 (23%) Mean 23% 17/250 (6.8%)Mean 6.8% SD 3.03% SD 6.22% Total \*Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)(0%)(0%)**Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0% \*Lung: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Lung: Hemangiosarcoma								
• • •		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
*Lung: Plasma Cell Tumor Malign	nant						•••••	
Č		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Lung: Sarcoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (00/)		0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node: Hemangiosarcoma								
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Lymph Node: Plasma Cell Tumor Malign	ant							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma				•••••	•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Lymph Node, Bronchial: Hemangiosarcoma				•••••			•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma					• • • • • • • • • • • • • • • • • • • •			
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 228
Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: FEED

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
_ymph Node, Mandibular: Mast Cell Tumor Malignant	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	ınt							
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
_ymph Node, Mesenteric: Fibrous Histiocytoma	•••••							
Fibrous Histocytoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma					•••••			
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 229

			Male				Female	
Lymph Node, Mesenteric: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Plasma Cell Tumor Malig								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland:								•••••
Adenoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	, ,		0/50 (0%)	0/50 (0%)	, ,
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 230

			Male				Female	
Mammary Gland: Carcinoma or Adenoma	1							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Mammary Gland: Fibroadenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
:Mammary Gland:					•••••			
Fibroma, Fibroadenoma	or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland:								
Fibroma, Fibroadenoma	ı, Carcinoma, o	or Adenoma 0/50 (0%)		0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/00 (0/0)		1/50 (2%)	0/50 (0%)	0/30 (0/0)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Mesentery: Fibrosarcoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (09/)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 231 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Mesentery: Hemangioma								
		0/50 (0%)	1/50 (20/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
lesentery: Sarcoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0 /8)		0/50 (0%)	0/50 (0%)	0/30 (0/8)
erall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
ose: Mast Cell Tumor Malignant		(00)		0.70			0.70	(00)
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
ral Cavity (Oral Mucosa, Ton Papilloma Squamous or Pa		nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
reian micidence	i Ulai	0/200 (0/0)	IVICALI U/0	3D 0/0	i Ulai	0/230 (0/0)	IVICALI U/0	30 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 232

Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%) 0/50 0/50 (0%)0/50 0/50 0/250 (0%) **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%) 0/50 (0%)0/50 0/50 (0%)**Overall Incidence** 0/200 (0%) SD 0% 0/250 (0%) SD 0% Total Mean 0% Total Mean 0% Choriocarcinoma 0/48 (0%)0/50 (0%)0/49 (0%)(0%) 0/48 0/46 (0%)**Overall Incidence** Total Mean 0% SD 0% 0/241 (0%) \*Ovary: Cystadenoma 0/481/50 (2%)3/49 (6%)1/46 2/48 (4%)(2%)**Overall Incidence** Total 7/241 (2.9%) Mean 2.89% SD 2.33% \*Ovary: **Fibrous Histiocytoma** 0/48(0%)0/50 (0%)0/49 (0%)(0%)0/48 (0%)0/46 **Overall Incidence** Total 0/241 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

vary:							
Granulosa Cell Tumor Benign							
Grandiosa Cen Tunior Benign			(4%)	0/50	(0%)	0/49	(0%)
verall Incidence	Total	2/48 ( 4/241 (1.6	,	0/46 Mean	(0%) ı 1.67%	SD	2.28%
eran moraence		4/241 (1.0		ivicai			2.2070
vary:							
Granulosa Cell Tumor Malignant		1/48 (	(2%)	0/50	(0%)	0/49	(0%)
			(0%)	0/46	(0%)	0/40	(070)
verall Incidence	Total	1/241 (0.4	11%)	Mear	0.42%	SD	0.93%
vary:							
Granulosa Cell Tumor: Benign, Malignant, NOS							
				0/50 0/46	(0%) (0%)	0/49	(0%)
verall Incidence	Total	5/241 (2.0	. ,		2.08%	SD	2.95%
vary: Hemangioma							
			(0%)	0/50	(0%)	0/49	(0%)
verall Incidence	Total	0/48 ( 0/241 (0%	(0%) 5)	0/46 Mear	(0%) ı 0%	SD	0%
		`	<i>'</i> •••••••				
vary:							
Hemangiosarcoma		0/48 (	(0%)	0/50	(0%)	0/49	(0%)
			(0%)	0/46	(0%)		, ,
verall Incidence	Total	0/241 (0%	<b>b</b> )	Mear	0%	SD	0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Page: 234

Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

	Male			Female	
Ovary:					
Leiomyosarcoma			0/48 (0%)	0/50 (0%)	0/49 (0%)
			0/48 (0%)	0/46 (0%)	0, 10 (0,70)
verall Incidence		Total	0/241 (0%)	Mean 0%	SD 0%
lvary:					
Luteoma					
			0/48 (0%) 0/48 (0%)	0/50 (0%) 0/46 (0%)	0/49 (0%)
verall Incidence		Total	0/241 (0%)	Mean 0%	SD 0%
Ovary:					
Plasma Cell Tumor Malignant			0/48 (0%)	0/50 (0%)	0/49 (0%)
			0/48 (0%)	0/46 (0%)	0/40 (070)
verall Incidence		Total	0/241 (0%)	Mean 0%	SD 0%
Ovary:					
Teratoma Benign			2/42 (22/)	2/22 (221)	
			0/48 (0%) 0/48 (0%)	0/50 (0%) 0/46 (0%)	0/49 (0%)
verall Incidence		Total	0/241 (0%)	Mean 0%	SD 0%
Ovary:					
Teratoma Malignant			0/48 (0%)	0/50 (0%)	0/49 (0%)
			0/48 (0%)	0/46 (0%)	3/40 (070)
Overall Incidence		Total	0/241 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: FEED

			Male				Female	
Ovary: Tubulostromal Adenoma							2/22 (22/)	
						0/48 (0%) 0/48 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence					Total	0/48 (0%) 0/241 (0%)	0/46 (0%) Mean 0%	SD 0%
Pancreas: Adenoma								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/246 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
overall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Pancreas: Carcinoma or Adenoma		•••••		•••••				•••••
Carcinoma of Adenoma		0/50 (0%) 0/49 (0%)	0/49 (0%)	1/49 (2%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	0/246 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis o Adenoma				•••••				•••••
		0/48 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		1/47 (2%) 5/49 (10%)	2/50 (4%) 2/49 (4%)	0/50 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.08%	SD 3.81%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 236 Report Date:04/29/2009

			Male				Female				
*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma  0/48 (0%) 0/50 (0%) 0/47 (0%) 0/50 (0%) 0/50 (0%)											
		0/48 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		0/47 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)			
verall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%			
Pituitary Gland: Pars Dista Carcinoma or Adenoma	alis or Unspecif	ied Site:			•••••						
		0/48 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		1/47 (2%) 5/49 (10%)	2/50 (4%) 2/49 (4%)	0/50 (0%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	10/245 (4.08%)	Mean 4.08%	SD 3.81%			
Pituitary Gland: Pars Inter Adenoma	media:										
		0/48 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		1/47 (2%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)			
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/245 (0.41%)	Mean 0.43%	SD 0.95%			
Pituitary Gland: Pars Inter Carcinoma or Adenoma	media:										
		0/48 (0%) 0/49 (0%)	0/48 (0%)	0/50 (0%)		1/47 (2%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%)			
verall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/245 (0.41%)	Mean 0.43%	SD 0.95%			
Prostate: Adenoma	•••••				•••••						
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)							
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 237 Report Date:04/29/2009

Contract/Lab: All Laboratories

Route: ORAL

Vehicle: FEED

			Male				Female	
*Prostate: Carcinoma or Adenoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Prostate: Hemangioma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Salivary Glands: Mast Cell Tumor Malignant								
grain		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: ORAL Vehicle: FEED Page: 238

			Male				Female	
#Seminal Vesicle: Adenoma		0/50 /00/		0/50 (00/)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma								
Ū		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skeletal Muscle:								
Myxosarcoma		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle:			•••••					
Rhabdomyosarcoma		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: FEED

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma or R	Rhabdomyom	a						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skeletal Muscle: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal Cell Adenoma or B Overall Incidence	<b>asosquamou</b> Total	s Tumor Benign 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma		Tumor Benign, or						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date:04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

			Male				Female	
#Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	us Tumor (malignant o	or .					
,		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/	<b>T</b>	0/50 (0%)	0/50 (0%)	00.00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, E Tumor (benign, maligna		Trichoepithelioma 0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
#Skin: Basal or Sq. Cell Carcin				•••••				
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant	ma, Adenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	1/50 (2%) SD 0.89%
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant Overall Incidence	ma, Ådenoma, thoma, Trichoep Total	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%		0/50 (0%) 1/250 (0.4%) 	0/50 (0%) Mean 0.4% 	SD 0.89%
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant Overall Incidence  Skin: Basosquamous Tumor	ma, Adenoma, thoma, Trichoer Total Benign	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0%  0/50 (0%)  Mean 0%	SD 0% 0/50 (0%) SD 0%	Total	0/50 (0%) 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0.4%  0/50 (0%) 0/50 (0%) Mean 0%	SD 0.89% 0/50 (0%) SD 0%
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant  Overall Incidence  Skin: Basosquamous Tumor	ma, Adenoma, thoma, Trichoer Total Benign	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0%  0/50 (0%)  Mean 0%	SD 0% 0/50 (0%) SD 0%	Total	0/50 (0%) 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0.4% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0.89% 0/50 (0%) SD 0%
Basal or Sq. Cell Carcin or B), Basal Cell Adeno Papilloma, Keratoacant  Dverall Incidence  Skin: Basosquamous Tumor  Dverall Incidence	ma, Adenoma, thoma, Trichoer Total Benign	Papilloma, Sq pithelioma 0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	Mean 0%  0/50 (0%)  Mean 0%	SD 0% 0/50 (0%) SD 0%	Total	0/50 (0%) 1/250 (0.4%) 0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0.4%  0/50 (0%) 0/50 (0%) Mean 0%	SD 0.89% 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: FEED

			Male				Female			
#Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or Fibrous Histiocytoma										
		1/50 (2%) 0/50 (0%)	3/50 (6%)	0/50 (0%)		2/50 (4%) 2/50 (4%)	5/50 (10%) 3/50 (6%)	3/50 (6%)		
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	15/250 (6%)	Mean 6%	SD 2.45%		
#Skin: Fibrosarcoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 1/50 (2%)	4/50 (8%) 3/50 (6%)	1/50 (2%)		
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	10/250 (4%)	Mean 4%	SD 2.83%		
#Skin: Fibrosarcoma, Sarcom	a. Myxosarcom	a or Fibrous								
#Skin: Fibrosarcoma, Sarcom Histiocytoma	a, Myxosarcom	1/50 (2%) 0/50 (0%)	2/50 (4%)	0/50 (0%)		2/50 (4%) 2/50 (4%)	5/50 (10%) 3/50 (6%)	3/50 (6%)		
Fibrosarcoma, Sarcom Histiocytoma	<b>a, Myxosarcom</b> Total	1/50 (2%)	2/50 (4%) Mean 1.5%	0/50 (0%) SD 1.91%	Total			3/50 (6%) SD 2.45%		
Fibrosarcoma, Sarcom Histiocytoma Overall Incidence		1/50 (2%) 0/50 (0%)	` ,	(111)	Total	2/50 (4%)	3/50 (6%)	,		
Fibrosarcoma, Sarcom Histiocytoma  Overall Incidence  Skin:		1/50 (2%) 0/50 (0%)	` ,	(111)	Total	2/50 (4%)	3/50 (6%)	,		
Fibrosarcoma, Sarcom Histiocytoma  Dverall Incidence  Skin: Fibrous Histiocytoma		1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%)	Mean `1.5%	SD 1.91%	Total Total	2/50 (4%) 15/250 (6%) 1/50 (2%)	3/50 (6%) Mean 6%	SD 2.45%		
Fibrosarcoma, Sarcom Histiocytoma  Overall Incidence  Skin: Fibrous Histiocytoma  Overall Incidence	Total Total	1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%) 0/50 (0%)	Mean 1.5%	SD 1.91% 0/50 (0%)		2/50 (4%) 15/250 (6%) 1/50 (2%) 0/50 (0%)	3/50 (6%) Mean 6% 0/50 (0%) 0/50 (0%)	SD 2.45% 0/50 (0%)		
Fibrosarcoma, Sarcom Histiocytoma  Overall Incidence  #Skin: Fibrous Histiocytoma  Overall Incidence	Total Total	1/50 (2%) 0/50 (0%) 3/200 (1.5%) 1/50 (2%) 0/50 (0%)	Mean 1.5%	SD 1.91% 0/50 (0%)		2/50 (4%) 15/250 (6%) 1/50 (2%) 0/50 (0%)	3/50 (6%) Mean 6% 0/50 (0%) 0/50 (0%)	SD 2.45% 0/50 (0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 242

			Male				Female	
#Skin: Hemangioma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/00 (0/0)		0/50 (0%)	1/50 (2%)	0/00 (0/0)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
‡Skin: Hemangiosarcoma					•••••			
		0/50 (0%)	0/50 (40/)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	2/50 (4%)	CD 4 040/	Total	2/50 (4%)	0/50 (0%)	CD 4 700/
overali incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
#Skin: Liposarcoma								
		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin:								
Myxosarcoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(575)		0/50 (0%)	0/50 (0%)	(1,1)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin:						• • • • • • • • • • • • • • • • • • • •		
Neurofibrosarcoma or S	chwannoma (	malignant or NOS) 0/50 (0%)		0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	(-,-)		0/50 (0%)	0/50 (0%)	(-,-,
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

Page: 243

			Male				Female	
#Skin: Neurofibrosarcoma, Neurofil malignant or NOS)	broma, or	Schwannoma (benign,						
g		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
∜Skin: Osteosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
∜Skin: Sarcoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 1.67%
Skin: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
∜Skin: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

nt System Page: 244
of Animal Groups Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female					
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma												
	J	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Skin: Squamous Cell Papilloma	·····											
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Skin: Squamous Cell Papilloma	or Papillom	a										
- <b>-</b>		0/50 (0%)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%				
Skin: Squamous Cell Papilloma	a. Papilloma.	Sauamous Cell										
Carcinoma or Keratoacar		·		0/50 (0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
Skin: Squamous Cell Papilloma	a, Papilloma,	or Keratoacanthoma				•••••	•••••					
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
		U/3U (U/n)	U/3U (U/n)			U/:)U (U:/o)	U/3U (U76)					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	,	(0%) (0%) (0%)	0/50 Maan	(0%)	0/50	(0%)		0/50	(00()	0/50			
	0/50 0/200 (	(0%)		(0%)	0/50	(0%)		0/50		0/50			
	0/200 (	` ,		(070)		()		0/50	(0%)	0/50	(0%)	1/50	(2%)
			iviean	0%	SD	0%	Total		(0%) (0.4%)	0/50 Mear	(0%) n 0.4%	SD	0.89%
											•••••		
	0/50	(0%)	0/50	(00/)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
otal		` '		` '	SD	በ%	Total		` ,		` '	SD	0.89%
Otai	0/200 (	0 70)	Mean	0 70	30	0 70	Total	1/230	(0.470)	ivicai	1 0.470	JD	0.0976
	0/50	(0%)	4/50	(00/)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
otal		` '		` '	SD	1%	Total		` ,		` '	SD	0%
	0/50	(0%)	4/50	(00/)	0/50	(0%)		1/50	(2%)	0/50	(0%)	0/50	(0%)
otal		` '			SD	10/_	Total		` ,		` '	SD	0.80%
	,	,							,				
	••••••							•••••					
	1/50	(2%)	0/50	(09/)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
otal		` '		` '	SD	1%	Total		` ,		` '	SD	0%
	otal	0/50 otal 0/200 (  0/50 0/50 otal 1/200 (  0/50 0/50 otal 1/200 (  1/50 0/50 otal 1/200 (	0/50 (0%) otal 0/200 (0%)  0/50 (0%) 0/50 (0%) otal 1/200 (0.5%)  0/50 (0%) 0/50 (0%) otal 1/200 (0.5%)  1/50 (2%) 0/50 (0%) otal 1/200 (0.5%)	0/50 (0%) 0/50 otal 0/200 (0%) Mean  0/50 (0%) 1/50 otal 1/200 (0.5%) Mean  0/50 (0%) 1/50 otal 1/200 (0.5%) Mean  1/50 (0%) 1/50 otal 1/200 (0.5%) Mean	0/50 (0%) 0/50 (0%)  otal 0/200 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)  otal 1/200 (0.5%) Mean 0.5%  1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)  otal 0/200 (0%) Mean 0% SD  0/50 (0%) 0/50 (2%)  otal 1/200 (0.5%) Mean 0.5% SD  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  otal 1/200 (0.5%) Mean 0.5% SD  1/50 (2%)  otal 1/50 (2%)  0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)  otal 0/200 (0%) Mean 0% SD 0%  0/50 (0%) 1/50 (2%)  otal 1/200 (0.5%) Mean 0.5% SD 1%  0/50 (0%) 1/50 (2%)  otal 1/200 (0.5%) Mean 0.5% SD 1%  1/50 (2%)  otal 1/200 (0.5%) Mean 0.5% SD 1%	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total  0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)  1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250  0/50 (0%) Mean 0% SD 0% Total 1/250  0/50 (0%) 1/50 (2%) 0/50  otal 1/200 (0.5%) Mean 0.5% SD 1% Total 0/250  0/50 (0%) 1/50 (2%) 0/50  otal 1/200 (0.5%) Mean 0.5% SD 1% Total 1/250  1/50 (2%) 0/50  otal 1/200 (0.5%) Mean 0.5% SD 1% Total 1/250  1/50 (2%) 0/50  0/50 (0%) 0/50 (0%) 0/50  O/50 (0%) 0/50 (0%) 0/50  O/50 (0%) 0/50 (0%) 0/50	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%)  0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 1/50 (2%)  0/50 (0%) 0/50 (0%)  1/50 (2%)  0/50 (0%) 0/50 (0%)  1/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mear  0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mear  0/50 (0%) 0/50 (0%	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4%  0/50 (0%) 0/50 (0%) Mean 0.4%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 1/250 (0.4%) Mean 0.4% SD  0/50 (0%) 0/50 (0%) Mean 0.4% SD  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 1/50 (2%) Total 0/250 (0%) 0/50 (0%)  0/50 (0%) 1/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 1/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%)  1/50 (2%) 0/50 (0%) Mean 0.4% SD  1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 246

Report Date:04/29/2009

Route: ORAL

Contract/Lab: All Laboratories

Strain: B6C3F1 Vehicle: FEED Length of Study: CHRONIC

			Male			Female				
*Spleen: Fibrous Histiocytoma		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/49 (0%)	0/48 (0%) 0/50 (0%)	0/48 (0%)		
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/245 (0%)	Mean 0%	SD 0%		
*Spleen: Hemangioma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/48 (0%)	0/48 (0%)		
Overall Incidence	Total	0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/245 (0%)	0/50 (0%) Mean 0%	SD 0%		
*Spleen: Hemangiosarcoma		0/50 (0%)		1/50 (2%)		2/50 (4%)	1/48 (2%)	1/48 (2%)		
Overall Incidence	Total	0/49 (0%) 3/199 (1.51%)	2/50 (4%) Mean 1.5%	SD 1.91%	Total	2/49 (4%) 6/245 (2.45%)	0/50 (0%) Mean 2.45%	SD 1.68%		
*Spleen: Mast Cell Tumor Malignar	nt	0.750 (001)		(00)		0.50	0/10 (00)	2/12 (22)		
Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/49 (0%) 0/245 (0%)	0/48 (0%) 0/50 (0%) Mean 0%	0/48 (0%) SD 0%		
*Spleen: Plasma Cell Tumor Maligr										
Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/49 (0%) 0/245 (0%)	0/48 (0%) 0/50 (0%) Mean 0%	0/48 (0%) SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 247
Report Date: 04/29/2009

**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: FEED

			Male				Female	
Stomach, Forestomach: Mast Cell Tumor Malignant								
· ·		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								•••••
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon	na Squamous						
		2/50 (4%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
Stomach, Forestomach: Squamous Cell Papilloma					•••••	•••••		•••••
		2/50 (4%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 2/50 (4%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
verall Incidence	Total	2/200 (1%)	Mean 1%	SD 2%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

11. Way2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 248

			Male				Female	
Stomach, Glandular: Carcinoma		0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/30 (0%)		0/50 (0%)	0/50 (0%)	0/30 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Testes: Adenoma			•••••		•••••			•••••
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
Testes:			•••••					•••••
Hemangiosarcoma		0/50 (0%)	2/52 (221)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%				
Thymus: Thymoma Benign								
		0/41 (0%) 0/48 (0%)	0/45 (0%)	0/44 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
Thymus: Thymoma Malignant		0/41 (0%)		0/44 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/48 (0%)	0/45 (0%)	0, (0,0)		0/49 (0%)	0/49 (0%)	0, 10 (0,0)
overall Incidence	Total	0/178 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Гhymus: Thymoma: Benign, Malign				•••••				
		0/41 (0%) 0/48 (0%)	0/45 (0%)	0/44 (0%)		0/49 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/178 (0%)	Mean 0%	SD 0%	Total	0/246 (0%)	Mean 0%	SD 0%
Гhyroid Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 1/50 (2%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
hyroid Gland: C-Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma				•••••	•••••			
2		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 250 Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%) 1/50 (2%)	0/48 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 1.15%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
*Thyroid Gland: Follicular Cell: Carcinoma						•••••		
		0/50 (0%) 0/50 (0%)	0/48 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%) 1/50 (2%)	0/48 (0%)	1/50 (2%)		1/50 (2%) 0/50 (0%)	0/48 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/198 (1.01%)	Mean 1%	SD 1.15%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%
#Tissue NOS: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: FEED

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			Male				Female	
Tissue NOS: Plasma Cell Tumor Malign	ant	0/50 (00%)		0/50 (00/)		0/50 /00/	0/50 /00/	0/50 /05/2
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue:	•••••							•••••
Squamous Cell Carcinoma	a	0/50 (0%)		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	OD 00/	<b>-</b>	0/50 (0%)	0/50 (0%)	00.00/
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Carcinoma	a or Papillon	na Squamous						
-	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Contract/Lab: All Laboratories

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
Tongue: Squamous Cell Papilloma		0/50 (00/)		0/50 (00/)		0/50 /00/	0/50 /00/	0/50 /00//
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tooth: Odontoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Jrinary Bladder:			•••••					
Hemangiosarcoma		0/50 (0%)		0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
		0/50 (0%)	0/50 (0%)	,		0/50 (0%)	0/50 (0%)	,
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Maligr								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Urinary Bladder: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma				•••••	•••••			
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma								
Garcinoma						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
#Uterus:	•••••	•••••		•••••	• • • • • • • • • • • • • • • • • • • •			
Hemangioma						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
					•••••			
#Uterus: Hemangiosarcoma								
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Leiomyoma 0/50 (0%)1/50 (2%)(0%)(0%)(0%)0/50 0/50 **Overall Incidence** Total 1/250 (0.4%) Mean 0.4% SD 0.89% #Uterus: Leiomyosarcoma 2/50 (4%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.79% #Uterus: **Polyp Stromal** (4%)0/50 (0%)(4%)0/50 (0%)4/50 (8%) **Overall Incidence** Mean 3.2% SD 3.35% Total 8/250 (3.2%)**#Uterus:** Sarcoma Stromal (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/250 **#Uterus:** Sarcoma Stromal or Polyp Stromal (0%)(4%)0/50 (0%)4/50 (8%)**Overall Incidence** Total 8/250 (3.2%)Mean 3.2% SD 3.35% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Schwannoma Malignant 1/50 (2%)0/50 (0%)(0%)(2%) (0%)1/50 0/50 **Overall Incidence** Total 2/250 (0.8%) Mean 0.8% SD 1.1% #Vagina: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Vagina: Squamous Cell Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% #Zymbal's Gland: Carcinoma 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** SD 0% SD 0.89% Total 0/200 (0%) Mean 0% Total 1/250 (0.4%) Mean 0.4% #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/200 (0%)Mean 0% SD 0% Total 1/250 (0.4%)Mean 0.4% SD 0.89%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 256

Report Date:04/29/2009

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	729 729 729 729	50 (1) 50 (1) 49 (1) 50 (1)	33(700) 38(696) 31(685) 40(697)	55.6 54.1 52.5 54.0	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
				Fen	nale		
Southern Research Institute Southern Research Institute Southern Research Institute Southern Research Institute	052011406 059601906 059601706 059601506	09/04/02 10/10/01 02/23/00 08/22/01	735 734 734 731	50 (5) 50 (5) 50 (5) 50 (5)	35(701) 36(693) 38(708) 35(705)	64.3 63.0 64.3 60.9	Sodium dichromate dihydrate (VI) Water disinfection byproducts (Bromochloroacetic acid) Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 257
Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
All Organs: Benign Tumors								
<b>g</b>		42/50 (84%) 32/50 (64%)	41/50 (82%)	25/49 (51%)		27/50 (54%) 29/50 (58%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	140/199 (70.35%)	Mean 70.26%	SD 15.66%	Total	117/200 (58.5%)	Mean 58.5%	SD 4.12%
All Organs: Malignant Tumors					•••••		•••••	
		31/50 (62%) 29/50 (58%)	36/50 (72%)	23/49 (47%)		22/50 (44%) 31/50 (62%)	38/50 (76%)	36/50 (72%)
verall Incidence	Total	119/199 (59.8%)	Mean 59.73%	SD 10.37%	Total	127/200 (63.5%)	Mean 63.5%	SD 14.27%
All Organs:  Malignant and Benign To	umors						•••••	
		49/50 (98%) 41/50 (82%)	47/50 (94%)	37/49 (76%)		36/50 (72%) 44/50 (88%)	43/50 (86%)	42/50 (84%)
verall Incidence	Total	174/199 (87.44%)	Mean 87.38%	SD 10.43%	Total	165/200 (82.5%)	Mean 82.5%	SD 7.19%
All Organs: Hemangioma					•••••			
_		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	2/50 (4%)	3/50 (6%)
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	6/200 (3%)	Mean 3%	SD 2.58%
All Organs: Hemangiosarcoma								
		4/50 (8%) 1/50 (2%)	3/50 (6%)	4/49 (8%)		2/50 (4%) 3/50 (6%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	12/199 (6.03%)	Mean 6.04%	SD 2.87%	Total	7/200 (3.5%)	Mean 3.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male		Female	
#All Organs: Hemangiosarcoma or He	emangioma					
nomangiosarooma or no	omangioma -	4/50 (8%) 2/50 (4%)	4/50 (8%) 4/49	(8%)	3/50 (6%) 3/50 (6%) 4/50 3/50 (6%)	) (8%)
Overall Incidence	Total	14/199 (7.04%)	Mean 7.04% SD	2.03% Total	13/200 (6.5%) Mean 6.5% S	D 1%
#All Organs: Histiocytic Sarcoma						
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	2/50 (4%) 1/50 (2%) 0/50 4/50 (8%)	0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD	0% Total	7/200 (3.5%) Mean 3.5% S	D 3.42%
#All Organs: Malignant Lymphoma: H or Undifferentiated Cell <sup>*</sup>						
		2/50 (4%) 0/50 (0%)	2/50 (4%) 0/49	(0%)	7/50 (14%) 18/50 (36%) 27/5 9/50 (18%)	50 (54%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2% SD	2.31% Total	61/200 (30.5%) Mean 30.5% S	D 18.36%
#All Organs: Mesothelioma: Benign, I						
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1% SD	2% Total	` ,	D 0%
All Organs: Mesothelioma: Malignan	ıt					
		2/50 (4%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%) 0/50 0/50 (0%)	0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1% SD	2% Total	0/200 (0%) Mean 0% S	D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Osteoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#All Organs: Osteosarcoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma or Osteo	ma				•••••			
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
*Adrenal Cortex: Adenoma								
		7/49 (14%) 6/50 (12%)	9/50 (18%)	3/49 (6%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	25/198 (12.63%)	Mean 12.6%	SD 4.98%	Total	0/199 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Mali	gnant							
	_	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Adrenal Cortex:								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Be								
		0/49 (0%) 1/49 (2%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Co	mplex							
•	•	0/49 (0%) 0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/197 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma Ma	alignant							
•	J	0/49 (0%) 0/49 (0%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/197 (0.51%)	Mean 0.51%	SD 1.02%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Adrenal Medulla: Pheochromocytoma: Be								
	. J., 22p.o.	0/49 (0%) 1/49 (2%)	0/50 (0%)	1/49 (2%)		0/49 (0%) 0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	2/197 (1.02%)	Mean 1.02%	SD 1.18%	Total	3/199 (1.51%)	Mean 1.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
*Bone Marrow: Hemangioma								
· ·		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma	•••••							
		1/49 (2%) 0/50 (0%)	1/50 (2%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/196 (1.02%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
*Bone Marrow: Plasma Cell Tumor Malig	ınant							
<u> </u>	•	0/49 (0%) 0/50 (0%)	0/50 (0%)	0/47 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone:								
Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Bone: Osteoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 262 Report Date: 04/29/2009

**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Bone: Osteosarcoma								
00.000		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	0/200 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteoma								
		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Bone: Sarcoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Benign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Brain: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 263

			Male			Female	
*Brain: Meningioma: Benign, Mal	lignant, NOS	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0% SD	0% Total	0/200 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/49	(0%)	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/199 (0%)	Mean 0% SD	,	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	Mean 0.5%	SD 1%
*Clitoral/Preputial Gland: Adenoma		0/50 (0%) 1/49 (2%)	0/48 (0%) 0/49	(0%)	0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.51% SD	1.02% Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/48 (0%) 0/49	(0%)	0/50 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/196 (0%)	Mean 0% SD	0% Total	0/47 (0%) 0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma							
Overall Incidence	Total	0/50 (0%) 1/49 (2%) 1/196 (0.51%)	0/48 (0%) 0/49  Mean 0.51% SD	(0%) 1.02% Total	0/50 (0%) 0/47 (0%) 0/190 (0%)	0/43 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ontrol Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Clitoral/Preputial Gland: Hemangioma								
-		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/50 (0%) 0/49 (0%)	0/48 (0%)	0/49 (0%)		0/50 (0%) 0/47 (0%)	0/43 (0%)	0/50 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%	Total	0/190 (0%)	Mean 0%	SD 0%
#Esophagus: Squamous Cell Carcinoma	• • • • • • • • • • • • • • • • • • • •							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Eye: Sarcoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Harderian Gland: Adenoma 6/50 (12%)(10%)(6%)4/50 (8%)(2%)(18%)5/50 (10%)6/50 (12%)**Overall Incidence** Total 19/199 (9.55%) Mean 9.53% SD 2.46% Total 20/200 (10%) Mean 10% SD 6.73% #Harderian Gland: Carcinoma 0/50 (0%)1/50 (2%)(2%)0/50 (0%)2/50 (4%)**Overall Incidence** Total Mean 0% SD 0% Total 6/200 (3%) Mean 3% SD 1.15% 0/199 (0%) #Harderian Gland: Carcinoma or Adenoma 6/50 (12%)(10%)(6%)(10%)3/50 (6%)(20%)5/50 (10%)8/50 (16%) **Overall Incidence** SD 6.22% Total 19/199 (9.55%)Mean 9.53% SD 2.46% Total 26/200 (13%)Mean 13% #Harderian Gland: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/199 (0%) SD 0% SD 0% Total Mean 0% Total 0/200 (0%) Mean 0% \*Heart: Hemangioma (0%)0/50 0/50 0/50 0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%)Mean 0% SD 0% Total 0/200 (0%)Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 266

			Male				Female	
Heart: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Heart: Sarcoma					•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Carcinoma								
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma							•••••	
		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	0/200 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Leiomyoma						•••••		
<b>,</b>		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date:04/29/2009

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male			Female	
#Intestine Large: Colon/Rect Leiomyosarcoma	um:						
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	(0%) Mean 0%	SD 0%
Intestine Small: Duodenum: Adenoma							
		1/50 (2%) 1/50 (2%)	3/50 (6%)	0/49 (0%)	0/50 0/50	(0%) 1/50 (2%) (0%)	0/50 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.5%	SD 2.52%	Total 1/200 (	(0.5%) Mean 0.5%	SD 1%
Intestine Small: Duodenum: Carcinoma							
		0/50 (0%) 0/50 (0%)	1/50 (2%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total 0/200 (	,	SD 0%
Intestine Small: Duodenum: Leiomyosarcoma		•••••					
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	(0%) Mean 0%	SD 0%
Intestine Small: Duodenum: Polyp Adenomatous							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 0/50	(0%) 0/50 (0%) (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (	,	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Intestine Small: Ileum: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Ileum: Polyp Adenomatous								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Adenoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ntestine Small: Jejunum: Carcinoma								
		0/50 (0%) 1/50 (2%)	1/50 (2%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	2/200 (1%)	Mean 1%	SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)0/50 0/50 Mean 0% 0/200 (0%) **Overall Incidence** Total 0/199 (0%) SD 0% Total Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) #Intestine Small: Jejunum: Polyp Adenomatous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1.02% SD 0% Total 1/199 (0.5%) Mean 0.51% Total 0/200 (0%) Mean 0% #Intestine Small: Site Unspecified: Adenoma 1/50 (2%)(0%)0/50 1/50 (2%)0/50 (0%)1/50 (2%)0/50 (0%)**Overall Incidence** 5/199 (2.51%) Mean 2.5% SD 2.52% 1/200 (0.5%) SD 1% Total Total Mean 0.5% #Intestine Small: Site Unspecified: Carcinoma (0%)0/50 2/50 (0%)1/50 (2%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 3/199 (1.51%)Mean 1.5% SD 1.91% Total 2/200 (1%) Mean 1% SD 1.15% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)(10%)(0%)1/50 (2%)(4%)(0%)(2%)(0%)1/50 0/50 3/200 (1.5%) Overall Incidence Total 7/199 (3.52%) Mean 3.5% SD 4.43% Total Mean 1.5% SD 1.91% #Intestine Small: Site Unspecified: Hemangiosarcoma 0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% 0/199 (0%) ..... #Intestine Small: Site Unspecified: Leiomvosarcoma (0%) 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/199 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Intestine Small: Site Unspecified: Polyp Adenomatous 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.51% SD 1.02% SD 0% Total Total 0/200 (0%) Mean 0% \*Islets, Pancreatic:

SD 2.57%

1/49

1/49

4/196 (2.04%)

Total

(2%)

Total

3/49

1/50

5/195

(6%)

(2%)

Mean 2.53%

(2.56%)

Adenoma

**Overall Incidence** 

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Report Date: 04/29/2009

1/49

SD 0%

Mean 2.04%

(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Control Animal Groups Report Date:04/29/2009
RAL

Page: 271

			Male				Female	
Islets, Pancreatic: Carcinoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
verall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/196 (0%)	Mean 0%	SD 0%
slets, Pancreatic: Carcinoma or Adenoma								
		3/49 (6%) 1/50 (2%)	1/50 (2%)	0/46 (0%)		1/49 (2%) 1/49 (2%)	1/49 (2%)	1/49 (2%)
Overall Incidence	Total	5/195 (2.56%)	Mean 2.53%	SD 2.57%	Total	4/196 (2.04%)	Mean 2.04%	SD 0%
Kidney: Renal Tubule: Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%
(idney: Renal Tubule: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	4/50 (8%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	5/199 (2.51%)	Mean 2.51%	SD 3.78%	Total	0/199 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor

act/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 272

			Male				Female	
Kidney: Renal Tubule: Hemangioma								
ū		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Plasma Cell Tumor Malign								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Liver: Cholangiocarcinoma				•••••			•••••	•••••
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
Liver: Fibrous Histiocytoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Liver: Hemangioma								
		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)		1/49 (2%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%	Total	2/198 (1.01%)	Mean 1.02%	SD 1.18%
Liver: Hemangiosarcoma								
		1/50 (2%) 0/50 (0%)	2/50 (4%)	1/49 (2%)		1/49 (2%) 2/50 (4%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	4/199 (2.01%)	Mean 2.01%	SD 1.63%	Total	4/198 (2.02%)	Mean 2.02%	SD 1.63%
Liver: Hepatoblastoma								
•		17/50 (34%) 1/50 (2%)	4/50 (8%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
overall Incidence	Total	22/199 (11.06%)	Mean 11%	SD 15.71%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
Liver: Hepatocellular Adenoma								
		36/50 (72%) 29/50 (58%)	27/50 (54%)	18/49 (37%)		14/49 (29%) 19/50 (38%)	27/50 (54%)	19/49 (39%)
overall Incidence	Total	110/199 (55.28%)	Mean 55.18%	SD 14.52%	Total	79/198 (39.9%)	Mean 39.84%	SD 10.52%
_iver: Hepatocellular Carcinoma			•••••					
		14/50 (28%) 24/50 (48%)	19/50 (38%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	3/49 (6%)
Overall Incidence	Total	71/199 (35.68%)	Mean 35.64%	SD 9.43%	Total	35/198 (17.68%)	Mean 17.61%	SD 9.08%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Liver:	Hawatahi							
Hepatocellular Carcinor	та от нератові	25/50 (50%) 24/50 (48%)	21/50 (42%)	14/49 (29%)		8/49 (16%) 10/50 (20%)	14/50 (28%)	4/49 (8%)
verall Incidence	Total	84/199 (42.21%)	Mean 42.14%	SD 9.67%	Total	36/198 (18.18%)	Mean 18.12%	SD 8.24%
_iver:					•••••			
Hepatocellular Carcinor	ma or Hepatoce	ellular Adenoma 42/50 (84%) 37/50 (74%)	34/50 (68%)	28/49 (57%)		17/49 (35%) 27/50 (54%)	31/50 (62%)	22/49 (45%)
verall Incidence	Total	141/199 (70.85%)	Mean 70.79%	SD 11.24%	Total	97/198 (48.99%)	Mean 48.9%	SD 11.77%
Hepatocellular Carcinor Hepatoblastoma Overall Incidence	Total	46/50 (92%) 37/50 (74%) 146/199 (73.37%)	35/50 (70%) Mean 73.29%	28/49 (57%) SD 14.4%	Total	17/49 (35%) 27/50 (54%) 97/198 (48.99%)	31/50 (62%) Mean 48.9%	22/49 (45%) SD 11.77%
iver: Hepatocholangiocarcin	oma	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/50 (0%) 0/199 (0%)	Mean 0%	SD 0%	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%
iver: Hepatocholangioma		0/50 (00/)	0/50 (00/)	0/40 (00/)		0/40 /00/	0/50 /00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER

Animal Groups Report Date:04/29/2009

Page: 275

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
*Liver: Ito Cell Tumor Benign		0/50 (00/)	0/50 /00/)	0/40 (00/)		0/40 (00/)	0/50 (00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant								
		0/50 (0%) 2/50 (4%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Plasma Cell Tumor Maligna	ant				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/198 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma				•••••		•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/198 (0.51%)	Mean 0.51%	SD 1.02%
*Lung: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/199 (0.5%)	Mean 0.51%	SD 1.02%	Total	0/200 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Lung: Alveolar/Bronchiolar Adenoma 15/50 (30%)(14%)1/50 (2%)(4%)1/50 (2%)6/50 (12%)3/50 (6%)7/200 (3.5%) SD 1.91% **Overall Incidence** Total 32/199 (16.08%) Mean 16.07% SD 9.64% Total Mean 3.5% \*Lung: Alveolar/Bronchiolar Carcinoma (6%) 3/50 (24%)(10%)2/50 (4%)(12%)(2%)4/50 (8%)6/50 (12%) **Overall Incidence** Total Mean 12.05% SD 8.15% Total 15/200 (7.5%) Mean 7.5% SD 5.26% 24/199 (12.06%) \*Lung: Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 16/50 (32%)15/50 (30%)12/49 (24%)2/50 (4%)8/50 (16%)(4%)(20%)(18%) 10/50 9/50 **Overall Incidence** Total 53/199 (26.63%) SD 5.44% 21/200 (10.5%) SD 7.55% Mean 26.62% Total Mean 10.5% \*Lung: Fibrosarcoma 1/50 (2%)0/50 (0%)0/49(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/199 (0.5%) 0/200 (0%) SD 0% **Overall Incidence** Total Mean 0.5% SD 1% Total Mean 0% \*Lung: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 277
Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
ung: Hemangiosarcoma								
riemangiosarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ung: Plasma Cell Tumor Mali						•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ung: Sarcoma				•••••		•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
ymph Node: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male		0/50 (0%) Total 0/200 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/200 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		Female			
Lymph Node: Hemangiosarcoma										
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		
-ymph Node: Plasma Cell Tumor Malignant				•••••	•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		
ymph Node: Sarcoma				•••••						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		
ymph Node, Bronchial: Hemangiosarcoma				•••••						
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	, ,	Mean 0%	SD 0%		
ymph Node, Mandibular: Fibrous Histiocytoma										
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%		

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Inc

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

Page: 279

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male				Female	
Lymph Node, Mandibular: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (09/)	0/50 (09/)	0/50 (0%)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
-ymph Node, Mandibular: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt							
· ·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
.ymph Node, Mesenteric: Fibrous Histiocytoma				•••••		•••••		
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ute: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: ORAL Vehicle: WATER

			Male				Female	
#Lymph Node, Mesenteric: Hemangiosarcoma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Plasma Cell Tumor Maliç			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoacanthoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

ntrol Animal Groups

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Report Date:04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Mammary Gland: Carcinoma or Adenoma	<u> </u>							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Mammary Gland: Fibroadenoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom	a or Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenom			•••••			•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%
Mesentery: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		3/50 (6%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 3%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 282

			Male				Female	
#Mesentery: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Mesentery: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 1.15%
Nose: Mast Cell Tumor Malign								
maer con ramer mang.		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary							
. apinoma oquamous o	аршоша	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 283

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(2%)(0%)0/50 (0%)0/50 1/200 (0.5%) **Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total Mean 0.5% SD 1% #Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or **Papilloma** 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)2/50 (4%)0/50 (0%)(0%) 0/50 **Overall Incidence** 0/199 (0%) SD 0% SD 2% Total Mean 0% Total 2/200 (1%) Mean 1% Choriocarcinoma 0/50 (0%)0/47 (0%)0/49 (0%)(2%) 1/50 **Overall Incidence** Total 1/196 (0.51%) Mean 0.5% SD 1% \*Ovary: Cystadenoma 1/50 (2%)(4%)0/49(0%)1/50 (2%)**Overall Incidence** 4/196 (2.04%) Total Mean 2.06% SD 1.74% \*Ovary: **Fibrous Histiocytoma** 0/50 (0%)(0%)0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Vehicle: WATER

Page: 284 Report Date: 04/29/2009

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

	Male		Female	
*Ovary: Granulosa Cell Tumor Benign				
Granulosa Cell Tumor Benign		0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/50 (2%) 1/196 (0.51%)	Mean 0.5%	SD 1%
Overall incluence		, ,		
*Ovary:				
Granulosa Cell Tumor Malignant		0/50 (0%)	0/47 (0%)	0/49 (0%)
		0/50 (0%)	,	,
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary:				
Granulosa Cell Tumor: Benign, Malignant, NOS				
		0/50 (0%) 1/50 (2%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	1/196 (0.51%)	Mean 0.5%	SD 1%
*Ovary:				
Hemangioma		0/50 (00/)	0/47 (00/)	0/40 (00/)
		0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma				
-		0/50 (0%) 0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence	Total	0/196 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups Page: 285

Report Date: 04/29/2009

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male **Female** \*Ovary: Leiomyosarcoma (0%)(0%)(0%)(0%) 0/50 **Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% \*Ovary: Luteoma 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% \*Ovary: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)(0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/196 (0%) Mean 0% \*Ovary: Teratoma Benign 0/50 (0%) (0%)0/50 (0%)**Overall Incidence** 0/196 (0%) Mean 0% SD 0% Total **Teratoma Malignant** (0%)(0%) 0/47 0/49 0/50 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: WATER

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Tubulostromal Adenoma						0/50 (0%)	0/47 (0%)	0/49 (0%)
Overall Incidence					Total	1/50 (2%) 1/196 (0.51%)	Mean 0.5%	SD 1%
*Pancreas: Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	0/195 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma								•••••
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Pancreas: Carcinoma or Adenoma								
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/46 (0%)		0/48 (0%) 0/49 (0%)	1/49 (2%)	0/49 (0%)
Overall Incidence	Total	0/195 (0%)	Mean 0%	SD 0%	Total	1/195 (0.51%)	Mean 0.51%	SD 1.02%
*Pituitary Gland: Pars Distalis o Adenoma								
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)
Overall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Vehicle: WATER

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Animal Groups Report Date:04/29/2009

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Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma	talis or Unspecif	ied Site:						
		0/49 (0%) 0/49 (0%)	0/50 (0%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	0/47 (0%)
verall Incidence	Total	0/193 (0%)	Mean 0%	SD 0%	Total	0/191 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Dist Carcinoma or Adenom					•••••			
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		3/48 (6%) 2/48 (4%)	4/48 (8%)	2/47 (4%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	11/191 (5.76%)	Mean 5.75%	SD 1.97%
Pituitary Gland: Pars Inte Adenoma	rmedia:				•••••			
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%
Pituitary Gland: Pars Inte Carcinoma or Adenom	rmedia:				•••••			
		0/49 (0%) 0/49 (0%)	1/50 (2%)	0/45 (0%)		0/48 (0%) 0/48 (0%)	0/48 (0%)	1/47 (2%)
verall Incidence	Total	1/193 (0.52%)	Mean 0.5%	SD 1%	Total	1/191 (0.52%)	Mean 0.53%	SD 1.06%
Prostate: Adenoma	•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)				
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male			Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/48 (0%)			
		0/50 (0%)	0/00 (0/0)	0/40 (070)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%			
*Prostate: Hemangioma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)			
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%			
*Salivary Glands: Carcinoma			•••••				
		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total 0/200 (0%)	Mean 0% SD 0%	
*Salivary Glands:			•••••				•••••
Carcinoma or Adenoma		0/49 (0%) 1/50 (2%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/198 (0.51%)	Mean 0.5%	SD 1%	Total 0/200 (0%)	Mean 0% SD 0%	
*Salivary Glands:			•••••				
Mast Cell Tumor Malignan	t	0/49 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/198 (0%)	Mean 0%	SD 0%	0/50 (0%) Total 0/200 (0%)	Mean 0% SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

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Species: MICE

Report Date:04/29/2009

Strain: B6C3F1 Length of Study: CHRONIC

Route: ORAL Vehicle: WATER

			Male			Female	
#Seminal Vesicle: Adenoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%			
#Skeletal Muscle: Fibrosarcoma							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Hemangiosarcoma							
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Myxosarcoma							
·		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma							
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total 0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female **#Skeletal Muscle:** Rhabdomyosarcoma or Rhabdomyoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/199 (0%) 0/200 (0%) **Overall Incidence** Total Mean 0% SD 0% Total Mean 0% SD 0% **#Skeletal Muscle:** Sarcoma 0/50 (0%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% Total 0/199 (0%) #Skin: Basal Cell Adenoma or Basosquamous Tumor Benign 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/199 (0%) Mean 0% Total 0/200 (0%) Mean 0% #Skin: Basal Cell Adenoma, Basosquamous Tumor Benign, or Trichoepithelioma 0/50 0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/199 (0%) SD 0% **Overall Incidence** Total Mean 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: **Basal Cell Carcinoma** 1/50 (2%)0/50 (0%)0/49 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0%

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Report Date: 04/29/2009

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Basal Cell Carcinoma or Basosquamous Tumor (malignant or NOS) 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)1/50 0/50 (0%)0/50 (0%)Mean 0.5% Mean 0% Overall Incidence Total 1/199 (0.5%)SD 1% Total 0/200 (0%)SD 0% #Skin: Basal Cell Carcinoma, Basal Cell Adenoma, Basosquamous Tumor (benign, malignant or NOS), or Trichoepithelioma 0/50 1/50 0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% #Skin: Basal or Sq. Cell Carcinoma, Carcinoma, Basosq. Tumor (M or B), Basal Cell Adenoma, Adenoma, Papilloma, Sq. Papilloma, Keratoacanthoma, Trichoepithelioma (2%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 2/199 (1.01%) SD 1.15% Total 0/200 (0%) Mean 0% SD 0% Mean 1% #Skin: **Basosquamous Tumor Benign** 0/50 (0%)0/50 (0%)(0%)0/50 0/50 (0%)**Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 0/200 (0%) Mean 0% SD 0% #Skin: Fibroma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 0/50 (0%)**Overall Incidence** Mean 1.01% SD 1.17% Mean 0% SD 0% Total 2/199 (1.01%) Total 0/200 (0%)

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Report Date: 04/29/2009

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 292

Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Fibroma, Fibrosarcoma, Fibrous Histiocytoma	, Sarcoma, Myx	koma, Myxosarcoma, o	r					
,		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	12/200 (6%)	Mean 6%	SD 2.31%
#Skin: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 4/50 (8%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	6/200 (3%)	Mean 3%	SD 3.46%
≄Skin: Fibrosarcoma, Sarcoma Histiocytoma	ı, Myxosarcom	a, or Fibrous						
•		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		2/50 (4%) 4/50 (8%)	2/50 (4%)	4/50 (8%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	12/200 (6%)	Mean 6%	SD 2.31%
Skin: Fibrous Histiocytoma		0/50 (00)		0/40 (00/)		0/50 (00/)	4/50 (001)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	4/200 (2%)	Mean 2%	SD 2.83%
Skin: Granular Cell Tumor Be	nign						•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/30 (0 /8)				0/30 (0/8)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 293

Report Date:04/29/2009

			Male				Female	
#Skin: Hemangioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%
#Skin: Hemangiosarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Liposarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma								
myxoodi ooma		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin:			•••••			•••••		
Neurofibrosarcoma or Se	chwannoma (ı	malignant or NOS) 0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Neurofibrosarcoma, Neurofi malignant or NOS)	broma, or	Schwannoma (benign,						
manghant of 1100)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Osteosarcoma			•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		1/50 (2%) 0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
#Skin: Schwannoma Malignant			•••••			•••••		•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 1/50 (2%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)1/199 (0.5%) SD 1% SD 0% Overall Incidence Total Mean 0.5% Total 0/200 (0%) Mean 0% **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)SD 1% SD 0% **Overall Incidence** Total 1/199 (0.5%) Mean 0.5% Total 0/200 (0%) Mean 0% #Skin: Squamous Cell Papilloma or Papilloma 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (0%)(0%) 0/50 0/50 **Overall Incidence** 1/199 (0.5%) SD 1% Total 0/200 (0%) SD 0% Total Mean 0.5% Mean 0% Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (0%) (0%) 0/50 (0%)(2%)0/50 (0%)(0%)1/50 0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/199 (0.5%) Mean 0.5% SD 1% Total 0/200 (0%) Mean 0% SD 0% Squamous Cell Papilloma, Papilloma, or Keratoacanthoma (0%)(0%)(0%)(0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** Mean 0.5% SD 1% SD 0% Total 1/199 (0.5%) Total 0/200 (0%) Mean 0%

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Report Date: 04/29/2009

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

ntrol Animal Groups

Page: 296

Report Date:04/29/2009

Route: ORAL Vehicle: WATER

			Male				Female	
#Skin: Trichoepithelioma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Skin: Sebaceous Gland: Carcinoma	•••••				•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Carcinoma or Adenoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Route: ORAL

Report Date: 04/29/2009

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Species: MICE Strain: B6C3F1

Vehicle: WATER Length of Study: CHRONIC

Male Female \*Spleen: **Fibrous Histiocytoma** 0/49 (0%)(0%)(0%)0/48 (0%)(0%)(0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/196 (0%) Mean 0% SD 0% Total 0/195 (0%) Mean 0% SD 0% \*Spleen: Hemangioma 0/49 (0%)0/48 (0%)(0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total Mean 0.5% SD 1% Total 0/195 (0%) Mean 0% SD 0% 1/196 (0.51%) \*Spleen: Hemangiosarcoma (2%) 2/49 (4%)1/50 1/48 (2%)(2%)(0%)1/50 (2%)0/48 (0%)**Overall Incidence** 2/195 (1.03%) SD 1.19% Total 6/196 (3.06%) Mean 3.08% SD 1.25% Total Mean 1.03% \*Spleen: Mast Cell Tumor Malignant 0/49 (0%)0/48(0%)(0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** 0/196 (0%) SD 0% SD 0% Total Mean 0% Total 0/195 (0%) Mean 0% \*Spleen: Plasma Cell Tumor Malignant (0%)0/49 0/50 (0%)0/47 0/48 0/49 (0%)0/50 (0%)(0%)0/50 0/48 (0%)**Overall Incidence** Total 0/196 (0%)Mean 0% SD 0% Total 0/195 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 298

Report Date:04/29/2009

			Male				Female	
Stomach, Forestomach: Mast Cell Tumor Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%)	1/49 (2%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1.01%	SD 1.17%	Total	0/200 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma c Overall Incidence	r <b>Papillon</b> Total	na Squamous 0/50 (0%) 0/50 (0%) 3/199 (1.51%)	2/50 (4%) Mean 1.51%	1/49 (2%) SD 1.92%	Total	1/50 (2%) 1/50 (2%) 3/200 (1.5%)	0/50 (0%) Mean 1.5%	1/50 (2%) SD 1%
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (00()	2/50 (40/)	0/40 (00/)		4/50 (20/)	0/50 (0%)	1/50 (20/)
		0/50 (0%) 0/50 (0%)	2/50 (4%)	0/49 (0%)		1/50 (2%) 1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 2%	Total	3/200 (1.5%)	Mean 1.5%	SD 1%
Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 299

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Stomach, Glandular: Carcinoma 0/50 (0%)(0%)(0%)0/50 (0%)(0%)(2%)(0%)0/50 (0%)0/50 **Overall Incidence** Total 0/199 (0%) Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% #Stomach, Glandular: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)(0%)(2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total Mean 0% SD 0% Total 1/200 (0.5%) Mean 0.5% SD 1% 0/199 (0%) \*Testes: Adenoma 0/50 (0%)1/50 (2%)(0%)1/50 (2%)**Overall Incidence** Total 2/199 (1.01%) Mean 1% SD 1.15% \*Testes: Hemangiosarcoma 0/50 (0%)(2%)0/50 (0%)**Overall Incidence** 1/199 (0.5%) Mean 0.51% SD 1.02% Total \*Thymus: Thymoma Benign 0/49 (0%)(0%) 0/46 0/46 0/49 (0%)0/44 (0%)0/46 (0%)**Overall Incidence** Total 0/181 (0%) Mean 0% SD 0% Total 0/185 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

Page: 300

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
Thymus: Thymoma Malignant								
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
verall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Fhymus: Thymoma: Benign, Maligna				•••••				
		0/49 (0%) 0/44 (0%)	0/46 (0%)	0/42 (0%)		0/46 (0%) 0/46 (0%)	0/49 (0%)	0/44 (0%)
verall Incidence	Total	0/181 (0%)	Mean 0%	SD 0%	Total	0/185 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma				•••••				
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	1/199 (0.5%)	Mean 0.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Thyroid Gland: Follicular Cell: Adenoma								
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%
*Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/199 (0%)	Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma			•••••	••••••				
		1/50 (2%) 3/50 (6%)	3/50 (6%)	0/48 (0%)		1/50 (2%) 1/49 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	7/198 (3.54%)	Mean 3.5%	SD 3%	Total	8/199 (4.02%)	Mean 4.01%	SD 2.3%
#Tissue NOS: Carcinoma			•••••					
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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Report Date:04/29/2009

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 302 Report Date:04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
#Tissue NOS: Plasma Cell Tumor Malignar	nt							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Fibroma					•••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma							•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
#Tongue: Squamous Cell Carcinoma o								
•	•	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	2/200 (1%)	Mean 1%	SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 303 Report Date: 04/29/2009

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male				Female	
#Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/200 (0.5%)	Mean 0.5%	SD 1%
Tooth: Odontoma				•••••	•••••	•••••	•••••	
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
· ·		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Jrinary Bladder: Hemangiosarcoma				•••••		•••••		
•		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Urinary Bladder: Plasma Cell Tumor Maligna							•••••	
		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 304

Report Date:04/29/2009

Route: ORAL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: WATER

			Male				Female	
Jrinary Bladder: Sarcoma		0/49 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/198 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%
Uterus: Adenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
Jterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence					Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
terus:			•••••			•••••		
Hemangioma					Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	1/50 (2%) SD 1%
·····						, ,		
Jterus: Hemangiosarcoma						0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Verall Incidence					Total	0/200 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 305

Report Date:04/29/2009

Route: ORAL Vehicle: WATER

	Male			Female	
tUterus:					
Leiomyoma			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%)		
verall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus:				•••••	
Leiomyosarcoma					
-			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence		Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%
veran mondence			` ,		
Uterus:					
Polyp Stromal					
			1/50 (2%) 1/50 (2%)	2/50 (4%)	1/50 (2%)
Overall Incidence		Total	5/200 (2.5%)	Mean 2.5%	SD 1%
Uterus:					
Sarcoma Stromal			0/50 (0%)	0/50 (0%)	0/50 (0%)
			0/50 (0%) 0/50 (0%)	0/30 (0%)	0/50 (0%)
Overall Incidence		Total	0/200 (0%)	Mean 0%	SD 0%
Uterus: Sarcoma Stromal or Polyp Stromal					
Carcoma Stromar or 1 oryp Stromar			1/50 (2%)	2/50 (4%)	1/50 (2%)
			1/50 (2%)	. ,	, ,
Overall Incidence		Total	5/200 (2.5%)	Mean 2.5%	SD 1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

			Male			Female           0/50 (0%) 0/50 (0%)         0/50 (0%)         0/50 (0%)           0/200 (0%)         Mean 0%         SD 0%           0/50 (0%) 0/50 (0%)         0/50 (0%)         0/50 (0%)           0/200 (0%)         Mean 0%         SD 0%           1/50 (2%) 0/50 (0%)         0/50 (0%)         0/50 (0%)           1/200 (0.5%)         Mean 0.5%         SD 1%           0/50 (0%) 0/50 (0%)         0/50 (0%)         SD 0%			
Uterus: Schwannoma Malignant									
							0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	` ,	Mean 0%	SD 0%	
				•••••					
Vagina: Squamous Cell Carcinor	na								
•							0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	` ,	Mean 0%	SD 0%	
······································					••••				
Squamous Cell Papillom	а					1/50 (2%)	0/50 (0%)	0/50 (0%)	
							0,00 (0,0)	0/00 (0/0)	
verall Incidence					Total	` ,			
Zymbal's Gland:									
Carcinoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	,	,			,	,	
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	,			
Zymbal's Gland: Carcinoma or Adenoma		•••••							
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/200 (0%)	Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

1: May2009

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

# Page: 307

Report Date:04/29/2009

## **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/03/02 06/25/02 05/08/00	728 730 729	50 (1) 50 (1) 50 (1)	37(682) 34(702) 39(710)	53.5 54.2 52.6	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory Southern Research Institute	059902806 059700308 059302008	10/02/02 06/24/02 05/08/00	727 729 732	50 (1) 50 (1) 50 (1)	31(692) 33(693) 33(674)	60.8 60.9 65.7	bis(2-Chloroethoxy)methane 1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:04/29/2009

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Species: MICE Strain: B6C3F1 Route: SKIN Vehicle: ETHANOL

			Male		31/50 (62%) 31/50 (62%) 26/50 (52%) tal 88/150 (58.67%) Mean 58.67% SD 5.77%  44/50 (88%) 46/50 (92%) 47/50 (94%) tal 137/150 (91.33%) Mean 91.33% SD 3.06%  1/50 (2%) 0/50 (0%) 2/50 (4%)		
#All Organs: Benign Tumors							
3		41/50 (82%)	40/50 (80%) 29	/50 (58%)	27/50 (54%) 39/50 (78%)	35/50 (70%)	
Overall Incidence	Total	110/150 (73.33%)	` '	SD 13.32% Total	101/150 (67.33%) Mean 67.33%	` '	
#All Organs: Malignant Tumors							
9		26/50 (52%)	27/50 (54%) 27	/50 (54%)	31/50 (62%) 31/50 (62%)	26/50 (52%)	
Overall Incidence	Total	80/150 (53.33%)	` ,	SD 1.15% Total	, , , , , , , , , , , , , , , , , , , ,	` '	
#All Organs:			•••••			•••••	
Malignant and Benign Tu	ımors						
o o		48/50 (96%)	45/50 (90%) 42	/50 (84%)	44/50 (88%) 46/50 (92%)	47/50 (94%)	
Overall Incidence	Total	135/150 (90%)		SD 6% Total	,		
#All Organs: Hemangioma							
		2/50 (4%)	0/50 (0%) 1/5	` '	` ,	` ,	
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2% Total	3/150 (2%) Mean 2%	SD 2%	
All Organs: Hemangiosarcoma							
J		5/50 (10%)	6/50 (12%) 0/5	60 (0%)	7/50 (14%) 1/50 (2%)	4/50 (8%)	
Overall Incidence	Total	11/150 (7.33%)	Mean 7.33%	SD 6.43% Total	12/150 (8 <sup>3</sup> %) Mean 8%	SD 6%	
All Organs: Hemangiosarcoma or He							
3	•	7/50 (14%)	6/50 (12%) 1/5	60 (2%)	8/50 (16%) 1/50 (2%)	6/50 (12%)	
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 6.43% Total	15/150 (10%) Mean 10%	SD 7.21%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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Report Date:04/29/2009

			Male			9/50 (18%) 14/50 (28%) 10/50 (20%) otal 33/150 (22%) Mean 22% SD 5.29%  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) otal 0/150 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/50 (0%) otal 0/150 (0%) Mean 0% SD 0%		
#All Organs: Histiocytic Sarcoma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		` ,	` '	` '
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	7/150 (4.67%)	Mean 4.67%	SD 2.31%
#All Organs: Malignant Lymphoma: or Undifferentiated Cell	Histiocytic, Lyr							
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%	Total	` ,	` ,	10/50 (20%) SD 5.29%
#All Organs: Mesothelioma: Benign,	Malignant, NO	<b>S</b> 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (09/)	0/50 (09/)	0/50 (00/)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	` '	` '
#All Organs: Mesothelioma: Maligna	nt	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	` '	` ,
#All Organs: Osteoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` '	` '
#All Organs: Osteosarcoma			(00)	(00)		400	(00)	(201)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Taral	2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
*Adrenal Cortex: Adenoma		6/49 (12%)	6/50 (12%)	5/50 (10%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	17/149 (11.41%)	Mean 11.41%	SD 1.23%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Plasma Cell Tumor Malignar	nt	0/49 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		0/40 (00/)	0/50 (004)	0(40 (00))	•••••	0/50 (00)	0/50 (404)	0/40 (00/)
Overall Incidence	Total	0/49 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 2/149 (1.34%)	2/50 (4%) Mean 1.33%	0/49 (0%) SD 2.31%
*Adrenal Medulla: Pheochromocytoma Comple	•x	0/49 (0%)	0/50 (0%)	0/49 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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0/50

(0%)

Mean 0%

0/50

SD 0%

(0%)

Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Adrenal Medulla: **Pheochromocytoma Malignant** 0/49 (0%)(2%)(0%)(0%)0/50 (0%)(0%)**Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 0/149 (0%) Mean 0% SD 0% ...... \*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS 0/49 (0%)0/49 1/50 (2%)0/50 2/50 0/49 (0%)**Overall Incidence** SD 2.31% Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 2/149 (1.34%) Mean 1.33% \*Bone Marrow: Hemangioma 0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/49 (0%)Overall Incidence Total 0/149 (0%) Mean 0% SD 0% Total 0/149 (0%) Mean 0% SD 0% \*Bone Marrow: Hemangiosarcoma (2%)(2%)0/49 (0%)(2%)(0%)(2%)1/50 1/50 0/50 1/49 2/149 (1.34%) SD 1.17% **Overall Incidence** Total Mean 1.33% SD 1.15% Total 2/149 (1.34%) Mean 1.35% \*Bone Marrow: **Plasma Cell Tumor Malignant** 0/50 (0%)(0%)0/49 (0%)0/50 0/50 0/49 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/149 Mean 0% SD 0% #Bone:

0/50

SD 0%

(0%)

Total

0/150 (0%)

Total

(0%)

0/150 (0%)

(0%)

Mean 0%

Hemangiosarcoma

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

control Animal Groups Report Date:04/29/2009
N

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			Male				Female	
#Bone: Osteoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
#Bone: Osteosarcoma or Osteom	 1a	0/50 (00/)	0/50 (00/)	0/50 /09/\		2/50 (40/)	4/50 (20/)	0/50 /09/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Brain: Meningioma Benign		0/50 (00/)	0/50 (00/)	0/40 /09/\		0/50 (00/)	0/50 (00/)	0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Brain: Meningioma Malignant		- (()						
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

SD 1.15%

Mean 0.67%

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female \*Brain: Meningioma: Benign, Malignant, NOS 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/149 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Brain: Schwannoma Malignant 0/50 (0%)(0%)0/49 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/149 (0%) Mean 0% Total 1/150 (0.67%)Mean 0.67% SD 1.15% \*Clitoral/Preputial Gland: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/46 (0%)Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% \*Clitoral/Preputial Gland: Carcinoma (0%)(0%)0/50 (0%)(0%)0/46 (0%)0/50 0/50 0/50 0/150 (0%) Mean 0% **Overall Incidence** Total Mean 0% SD 0% Total 0/146 (0%) SD 0% \*Clitoral/Preputial Gland: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/46 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% \*Clitoral/Preputial Gland: Hemangioma 0/50 (0%)(0%)0/50 (0%)(2%)0/50 (0%)0/46 (0%)

SD 0%

Total

1/146 (0.68%)

Mean 0%

Total

0/150 (0%)

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009 Vehicle: ETHANOL

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			Male			Female           O/50 (0%)         O/50 (0%)         O/46 (0%)           Total         O/146 (0%)         Mean 0%         SD 0%           O/50 (0%)         O/50 (0%)         O/46 (0%)           Total         O/146 (0%)         Mean 0%         SD 0%			
*Clitoral/Preputial Gland: Hemangiosarcoma									
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/46 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%	
*Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)				0/46 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	` ,	` '	` '	
#Esophagus: Squamous Cell Carcinoma		•••••	•••••			•••••			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Eye: Sarcoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%	
#Harderian Gland: Adenoma									
		10/50 (20%)	7/50 (14%)	9/50 (18%)		3/50 (6%)	6/50 (12%)	9/50 (18%)	
Overall Incidence	Total	26/150 (17.33%)	Mean 17.33%	SD 3.06%	Total	18/150 (12%)	Mean 12%	SD 6%	
#Harderian Gland: Carcinoma		0/50 (40)	0/50 (00/)	0/50 (40/)		0/50 /00/	0/50 (400)	4/50 (00/)	
		2/50 (4%)	0/50 (0%)	2/50 (4%)		0/50 (0%)	2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	3/150 (2%)	Mean 2%	SD 2%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female #Harderian Gland: Carcinoma or Adenoma 12/50 (24%)(14%)10/50 (20%)(6%)8/50 (16%)10/50 (20%)**Overall Incidence** Total 29/150 (19.33%) Mean 19.33% SD 5.03% Total 21/150 (14%) Mean 14% SD 7.21% #Harderian Gland: Sarcoma 1/50 (2%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 0/150 Mean 0% \*Heart: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% \*Heart: Hemangiosarcoma (0%)(0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 **Overall Incidence** SD 1.15% Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% \*Heart: Sarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% #Intestine Large: Cecum: Carcinoma (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male	Female
Intestine Large: Cecum: Carcinoma or Adenoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Intestine Large: Cecum: Leiomyoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Large: Colon/Rectum: Leiomyosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Duodenum: Adenoma				
		0/50 (0%)	0/50 (0%) 1/50 (2%	
verall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.159	5% Total 1/150 (0.67%) Mean 0.67% SD 1.15%
ntestine Small: Duodenum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%	%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Duodenum: Leiomyosarcoma				0/10 /00/ 0/10 /00/ 0/10 /00/
		0/50 (0%)	0/50 (0%) 0/50 (0%	, , , , , , , , , , , , , , , , , , , ,
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Ileum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Jejunum: Carcinoma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

(2%)

SD 1.15%

1/50

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)(0%)(0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Jejunum: Leiomyosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)SD 0% **Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% #Intestine Small: Jejunum: **Polyp Adenomatous** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Intestine Small: Site Unspecified: Adenoma (0%)(0%)(2%)0/50 (0%)(2%)0/50 0/50 1/50 1/50 **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Intestine Small: Site Unspecified: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% ...... #Intestine Small: Site Unspecified:

1/50

(2%)

SD 1.15%

0/50

Total

1/150 (0.67%)

(0%)

0/50

(0%)

Mean 0.67%

Total

0/50

1/150 (0.67%)

(0%)

0/50

(0%)

Mean 0.67%

Carcinoma or Adenoma

**Overall Incidence** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

				Ма	ale						Fem	ale		
#Intestine Small: Site Unspecif	ied:													
•		0/50	(0%)	0/50	(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150 (	0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD	0%
#Intestine Small: Site Unspecif Leiomyosarcoma												(00()	0/50	(00/)
On a self-level de se e	T-1-1	0/50	(0%)		(0%)	0/50	(0%)	T-1-1	0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150 (	,	Mean			0%	Total	0/150	` ,		n 0%	SD	0%
#Intestine Small: Site Unspecif Polyp Adenomatous														
		0/50	(0%)		(0%)	0/50	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/150 (	0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n 0%	SD	0%
*Islets, Pancreatic: Adenoma														
		0/50	(0%)		(0%)	1/49	(2%)		0/50	(0%)	1/50	(2%)	0/50	(0%)
Overall Incidence	Total	1/149 (	0.67%)	Mean	0.68%	SD	1.18%	Total	1/150	(0.67%)	Mea	n 0.67%	SD	1.15%
*Islets, Pancreatic: Carcinoma							•••••		•••••	•••••	•••••		• • • • • • • • • • • • • • • • • • • •	
		0/50	(0%)	0/50	(0%)	0/49	(0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
Overall Incidence	Total	0/149 (	0%)	Mean	0%	SD	0%	Total	0/150	(0%)	Mea	n `0%´	SD	0%
*Islets, Pancreatic: Carcinoma or Adenoma		0/50	(00/)	0/50	(0%)	1/49	(2%)	•••••	0/50	(00/)	1/50	(20/)	0/50	(00/)
Overell Incidence	Total		(0%)		` '		` ,	Total		(0%)	1/50	(2%)		(0%)
Overall Incidence	Total	1/149 (	(%/م.	iviean	0.68%	2D	1.18%	Total	1/150	(0.67%)	iviea	n 0.67%	2D	1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Kidney: Renal Tubule: Adenoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (00/)	0/50 (0%)	0/40 (00/)		0/50 (00/)	0/50 (0%)	0/40 /00/
Overall Incidence	Total	0/50 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Overall illicidence	TOtal	0/148 (0%)	IVICALI 070	30 0%	I Olai	0/149 (076)	IVICALI U/0	30 0/6
*Kidney: Renal Tubule: Carcinoma or Adenoma		- ( ( ( ( ( ( ( ( ( (	- ( ( ( ( ( ( ( ( ( (	(00)		- (·)	- ( ( ( ( ( ( ( ( ( (	
Occupation of days as	T-1-1	0/50 (0%)	0/50 (0%)	0/48 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangioma								
Overall Insidence	Tatal	0/50 (0%)	0/50 (0%)	0/48 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/148 (0%)	Mean 0%	SD 0%	Total	0/149 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Plasma Cell Tumor Maligna	nt	0/50 (00/)	0/50 (09/)	0/49 (00/)		0/50 (09/)	0/50 (09/)	0/40 (09/)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Overall incluence	IUlai	0/148 (0%)	IVICALI U70	3D 0%	Total	0/149 (070)	IVICALI U70	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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Report Date:04/29/2009

			Male		% Total 0/150 (0%) Mean 0% SD 0% 6) 0/50 (0%) 1/50 (2%) 0/50 (0%			
*Liver: Cholangiocarcinoma  Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	` ,	` '	` '
Overall illelidelide	I Olai	1/130 (0.07 /8)	iviean 0.07 /6	30 1.13%	I Olai	0/130 (0/8)	Mean 076	
*Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,		SD 1.15%
*Liver: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma	•	1/50 (2%)	4/50 (20/)	0/50 (00/)		2/50 (49/)	4/50 (20/)	4/50 /00/)
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	2/50 (4%) 4/150 (2.67%)	1/50 (2%) Mean 2.67%	1/50 (2%) SD 1.15%
*Liver: Hepatoblastoma		2/50 (4%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Liver: Hepatocellular Adenoma	•	22/50 (669/)	25/50 (7700/)	49/50 (259/)		22/50 (449/)	24/50 (620()	24/50 (420/)
Overall Incidence	Total	33/50 (66%) 86/150 (57.33%)	35/50 (70%) Mean 57.33%	18/50 (36%) SD 18.58%	Total	22/50 (44%) 74/150 (49.33%)	31/50 (62%) Mean 49.33%	21/50 (42%) SD 11.02%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
Liver: Hepatocellular Carcinoma								
		14/50 (28%)	17/50 (34%)	20/50 (40%)		3/50 (6%)	8/50 (16%)	10/50 (20%)
Overall Incidence	Total	51/150 (34%)	Mean 34%	SD 6%	Total	21/150 (14%)	Mean 14%	SD 7.21%
.iver: Hepatocellular Carcinoma or					•••••			
riepatocentiai Garemonia or	Перагов	15/50 (30%)	19/50 (38%)	20/50 (40%)		3/50 (6%)	9/50 (18%)	10/50 (20%)
Overall Incidence	Total	54/150 (36%)	Mean 36%	SD 5.29%	Total	22/150 (14.67%)	Mean 14.67%	SD 7.57%
_iver: Hepatocellular Carcinoma or	Hepatoc	ellular Adenoma 40/50 (80%)	41/50 (82%)	35/50 (70%)	•••••	22/50 (44%)	32/50 (64%)	29/50 (58%)
verall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 6.43%	Total	83/150 (55.33%)	Mean 55.33%	SD 10.26%
Liver: Hepatocellular Carcinoma, H Hepatoblastoma	epatocell	ular Adenoma, or 40/50 (80%)	41/50 (82%)	35/50 (70%)		22/50 (44%)	32/50 (64%)	29/50 (58%)
Overall Incidence	Total	116/150 (77.33%)	Mean 77.33%	SD 6.43%	Total	83/150 (55.33%)	Mean 55.33%	SD 10.26%
		0/50 (00/)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Liver: Hepatocholangioma		0/50 (00/)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
hyarall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 323

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

emale
(0%) 0/50 (0%)
ean 0% SD 0%
(0%) 0/50 (0%)
ean 0% SD 0%
(0%) 0/50 (0%) ean 0% SD 0%
(0%) 0/50 (0%)
ean 0% SD 0%
(0%) 0/50 (0%) ean 0% SD 0%
(4%) 4/50 (8%)
ean 4.67% SD 3.06%
)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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Report Date:04/29/2009

			Male	Female
*Lung: Alveolar/Bronchiolar Ca	rcinoma	E/EQ (400/)	C/EO (420) 2/EO (420)	A/EQ (99/) 2/EQ (99/) 0/FQ (99/)
Overall Incidence	Total	5/50 (10%) 13/150 (8.67%)	6/50 (12%) 2/50 (4%) Mean 8.67% SD 4.16%	4/50 (8%) 3/50 (6%) 0/50 (0%) Total 7/150 (4.67%) Mean 4.67% SD 4.16%
:Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Alv	veolar/Bronchiolar		
Overall Incidence	Total	11/50 (22%) 34/150 (22.67%)	15/50 (30%) 8/50 (16%) Mean 22.67% SD 7.02%	5/50 (10%) 5/50 (10%) 4/50 (8%) Total 14/150 (9.33%) Mean 9.33% SD 1.15%
Lung: Fibrosarcoma		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%) Mean 0.67% SD 1.15%
Lung: Hemangiosarcoma		0/50 (09/)	0/50 (09/) 0/50 (09/)	0/50 (09/) 0/50 (09/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%
Lung: Plasma Cell Tumor Maliç	gnant	0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Lung: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
£Lymph Node: Hemangioma	•••••	0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 /00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Lymph Node: Plasma Cell Tumor Malign	nant							•••••
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Lymph Node: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Lymph Node, Bronchial: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#Lymph Node, Mandibular: Hemangiosarcoma		0.700 (004)	(004)	(00)		0/20 (00)	2/22 (224)	0/20 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mandibular: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Plasma Cell Tumor Maligna	nt	(00)	(00)	(00)		0.000	(00)	0/20 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Lymph Node, Mesenteric: Hemangioma 0/50 (0%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% ..... **#Lymph Node, Mesenteric:** Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 0/50 (0%)(0%)SD 0% **Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% **#Lymph Node, Mesenteric: Plasma Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mammary Gland: Adenoacanthoma 0/50 (0%)(0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 0/50 0/50 Mean 0% Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Total 0/150 (0%) SD 0% #Mammary Gland: Adenoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% 

1/50

(2%)

SD 1.15%

2/50

Total

3/150 (2%)

(4%)

0/50

(0%)

Mean 2%

Total

1/50

2/150 (1.33%)

(2%)

0/50

(0%)

Mean 1.33%

#Mammary Gland: Carcinoma

**Overall Incidence** 

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Report Date: 04/29/2009

(2%)

1/50

SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
#Mammary Gland: Carcinoma or Adenoma	a							
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Mammary Gland: Fibroadenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenom	a or Adenoma	0/50 (00)		(00)			(201)	(00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mammary Gland: Fibroma, Fibroadenom	a, Carcinoma, o	or Adenoma						
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) Mean 2%	1/50 (2%) SD 2%
#Mesentery: Fibrosarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Mesentery: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Mesentery: Sarcoma		0/50 (00/)	0/50 (00)	0/50 (001)		4/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
*Nose: Mast Cell Tumor Malignar	nt	0/50 (00()	0/50 (00/)	0/40 (00/)		0/50 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or F	ongue, Phary	, ,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom	ongue, Phary	, ,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Squamous Cell Carcinom Papilloma	ongue, Phary							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 330

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female
*Ovary: Choriocarcinoma		0/50 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%
*Ovary: Cystadenoma			
Overall Incidence	Total	2/50 (4%) 6/149 (4.03%)	3/50 (6%) 1/49 (2%) Mean 4.01% SD 1.98%
*Ovary: Fibrous Histiocytoma			
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	1/50 (2%) 0/49 (0%) Mean 0.67% SD 1.15%
*Ovary: Granulosa Cell Tumor Benign			
Overall Incidence	Total	0/50 (0%) 1/149 (0.67%)	0/50 (0%) 1/49 (2%) Mean 0.68% SD 1.18%
*Ovary: Granulosa Cell Tumor Malignant			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%
*Ovary:			
Granulosa Cell Tumor: Benign, Malignant, NOS		0/50 (0%)	0/50 (0%) 1/49 (2%)
Overall Incidence	Total	1/149 (0.67%)	Mean 0.68% SD 1.18%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date:04/29/2009

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Total (	0/50					
Total (	0/50					
Total C		` '	,	,		0%)
Total 1	0/50 1/149 (0	` '	,	,		2%) 8%
Total (	0/50 0/149 (0	` '	,	,		0%)
Total (	0/50 0/149 (0	` '	,	,		0%)
	•••••	•••••	•••••			
Total (	0/50 0/149 (0	` '	,	,		0%)
		•••••				
Total (	0/50 0/149 (0	` '	,	,	,	0%)
	Total  Total  Total	O/50 Total 0/149 ((  0/50 Total 1/149 ((  0/50 Total 0/149 ((  0/50 Total 0/149 ((  0/50 Total 0/149 ((  0/50 Total 0/149 ((  0/50	O/50 (0%)  Total 0/149 (0%)  O/50 (0%)  O/50 (0%)  Total 0/149 (0%)  O/50 (0%)  Total 0/149 (0%)  Total 0/149 (0%)  O/50 (0%)  O/50 (0%)  O/50 (0%)	Total 0/149 (0%) Mean  0/50 (0%) 0/50 (  Total 1/149 (0.67%) Mean  0/50 (0%) 0/50 (  Total 0/149 (0%) Mean  0/50 (0%) 0/50 (  Total 0/149 (0%) Mean  0/50 (0%) 0/50 (  Total 0/149 (0%) Mean	Total 0/149 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 1/  Total 1/149 (0.67%) Mean 0.68%  0/50 (0%) 0/50 (0%) 0/  Total 0/149 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/  Total 0/149 (0%) Mean 0%  1/  0/50 (0%) 0/50 (0%) 0/  Mean 0%  0/50 (0%) 0/50 (0%) 0/  Total 0/149 (0%) Mean 0%	Total 0/149 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 1/49 (2  Total 1/149 (0.67%) Mean 0.68% SD 1.1  0/50 (0%) 0/50 (0%) 0/49 (0  Total 0/149 (0%) Mean 0% SD 0%  0/50 (0%) 0/50 (0%) 0/49 (0%)  Total 0/149 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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			Male				Female	
*Ovary: Teratoma Malignant						0/50 (00/)	0/50 (00/)	0/40 (004)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Ovary: Tubulostromal Adenoma							0/50 (00/)	2/12 (22/)
Overall Incidence					Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Pancreas: Adenoma		0/50 (00/)	0/50 (0%)	0/40 /00/		0/50 (00)	0/50 (0%)	0/50 /00/
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Carcinoma		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pituitary Gland: Pars Distalis Adenoma	or Unspecif	fied Site:						
Overall Incidence	Total	1/50 (2%) 1/148 (0.68%)	0/50 (0%) Mean 0.67%	0/48 (0%) SD 1.15%	Total	4/49 (8%) 13/147 (8.84%)	5/50 (10%) Mean 8.83%	4/48 (8%) SD 1.01%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 333

Report Date: 04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)(0%)(0%)0/49 0/50 (0%)(2%)**Overall Incidence** Total 0/148 (0%) Mean 0% SD 0% Total 1/147 (0.68%) Mean 0.69% SD 1.2% \*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma (0%)0/48 (0%)(2%)0/50 4/49 (8%)5/50 (10%)5/48 (10%)**Overall Incidence** SD 1.2% Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total (9.52%)Mean 9.53% \*Pituitary Gland: Pars Intermedia: Adenoma 1/50 (2%)0/50 (0%)0/48 (0%)0/49 (0%)(2%)0/48 (0%)1/50 **Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 1/147 (0.68%) Mean 0.67% SD 1.15% \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma (2%)(0%)0/48 (0%)(2%)(0%)1/50 0/50 1/50 0/48 SD 1.15% **Overall Incidence** Total 1/148 (0.68%) Mean 0.67% SD 1.15% Total 1/147 (0.68%) Mean 0.67% \*Prostate: Adenoma 0/50 (0%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% \*Prostate: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% Total Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 334

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Prostate: Hemangioma								
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma			(201)	(20)				(104)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Salivary Glands: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Seminal Vesicle: Adenoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%				
#Skeletal Muscle: Fibrosarcoma		2/22 (201)						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 335

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma				0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Myxosarcoma								-/
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma	•••••							
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyom						2/20 (00)	0/20 (00)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma or Ba	asosquamou						2/20 (00)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 336

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Skin: Basal Cell Adenoma, E Trichoepithelioma	Basosquamous <sup>*</sup>	Tumor Benign, or						
тионооринонони		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
kin:								
Basal Cell Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	Mean 0.67%	0/50 (0%) SD 1.15%
rerail illelidelide	Total	0/130 (070)	Wear 070	3D 070	Total	1/130 (0.07/0)	Weatt 0.0770	3D 1.1370
skin: Basal Cell Carcinoma NOS)	or Basosquamo	ous Tumor (malignant o	······································					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
erall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Basal Cell Carcinoma, Tumor (benign, malign	nant or NOS), or	Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign		Trichoepithelioma	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
	Totalinoma, Carcinoroma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma	Mean 0%	SD 0% ′	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Basal Cell Carcinoma, Tumor (benign, malign verall Incidence	Totalinoma, Carcinoroma, Adenoma,	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq	` '	` '	Total 	` ,	` '	` ,
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence Skin: Basal or Sq. Cell Carci or B), Basal Cell Adend Papilloma, Keratoacan verall Incidence	Total inoma, Carcinoroma, Adenoma, thoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / O/50 (0%) SD 0%	Total	1/150 (0.67%)  0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15% 
Basal Cell Carcinoma, Tumor (benign, malign verall Incidence  Skin: Basal or Sq. Cell Carci or B), Basal Cell Adeno Papilloma, Keratoacan	inoma, Carcinor oma, Adenoma, ithoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / O/50 (0%) SD 0%	Total	1/150 (0.67%)  0/50 (0%) 1/150 (0.67%)	Mean 0.67%  1/50 (2%)  Mean 0.67%	SD 1.15%  0/50 (0%) SD 1.15%
Basal Cell Carcinoma, Tumor (benign, maligr verall Incidence  Skin: Basal or Sq. Cell Carci or B), Basal Cell Adeno Papilloma, Keratoacan verall Incidence	inoma, Carcinor oma, Adenoma, ithoma, Trichoe	Trichoepithelioma 0/50 (0%) 0/150 (0%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 0/50 (0%) 0/150 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0% / O/50 (0%) SD 0%	Total	1/150 (0.67%)  0/50 (0%) 1/150 (0.67%)	Mean 0.67%	SD 1.15% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 337

Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Fibroma (0%)(0%)(2%)(0%)(0%)0/150 (0%) **Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% Total Mean 0% SD 0% #Skin: Fibroma, Fibrosarcoma, Sarcoma, Myxoma, Myxosarcoma, or **Fibrous Histiocytoma** 0/50 (2%)0/50 (2%)1/50 (2%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% 2/150 (1.33%) Mean 1.33% SD 1.15% Total #Skin: Fibrosarcoma 0/50 0/50 (0%)(0%)(2%)SD 0% SD 1.15% Overall Incidence Total 0/150 (0%) Mean 0% Total 1/150 (0.67%)Mean 0.67% #Skin: Fibrosarcoma, Sarcoma, Myxosarcoma, or Fibrous Histiocytoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(2%)1/50 (2%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 2/150 (1.33%) Mean 1.33% SD 1.15% **Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total Total 0/150 (0%) Mean 0% 0/150 (0%) Mean 0% SD 0% #Skin: **Granular Cell Tumor Benign** (0%)(0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Page: 338

			Male				Female	
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
#Skin: Hemangiosarcoma		1/50 (2%)	2/50 (4%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	2/50 (4%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	3/150 (2%)	Mean 2%	SD 2%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Myxosarcoma							•••••	•••••
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neurofibrosarcoma or S	Schwannoma (r	malignant or NOS) 0/50 (0%)	0/50 (0%)	0/50 (0%)		2/50 (4%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	3/150 (2%)	Mean 2%	SD 2%
#Skin: Neurofibrosarcoma, Ne malignant or NOS)	urofibroma, or	Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Osteosarcoma 0/50 (0%)(0%)0/50 (0%)(0%)(0%)0/150 (0%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Skin: Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0% Total (0.67%)Mean 0.67% SD 1.15% #Skin: Schwannoma Malignant 0/50 (0%)0/50 (0%)0/50 (0%)2/50 (4%)(2%)(0%)1/50 0/50 Overall Incidence Total 0/150 (0%) Mean 0% SD 0% Total 3/150 (2%) Mean 2% SD 2% #Skin: Squamous Cell Carcinoma (0%) (0%)(0%)(0%)(0%)0/50 0/50 0/50 0/50 0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)0/50 (0%)(2%)(0%)SD 0% **Overall Incidence** Total 0/150 (0%) Mean 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% #Skin: Squamous Cell Papilloma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 340

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male				Female	
na or Papillom		0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
na, Papilloma, Inthoma	Squamous Cell						
<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
l otal	0/150 (0%)	Mean 0%	SD 0%	l otal	0/150 (0%)	Mean 0%	SD 0%
na, Papilloma,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
	0/50 (00/)	0/50 (00)	0/50 /00/)		0/50 (00)	0/50 (00)	0/50 (00/)
Total	` ,	0/50 (0%) Mean 0%	` '	Total	` ,	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
	Total  na, Papilloma, Inthoma  Total  na, Papilloma, Total  Total	na, Papilloma, Squamous Cell Inthoma  0/50 (0%)  Total 0/150 (0%)  na, Papilloma, or Keratoacanthoma 0/50 (0%)  Total 0/150 (0%)	10	Na or Papilloma	O/50	Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)  Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%)	na or Papilloma

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Page: 341

Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	0/49 (0%)
Overall Incidence	Total	0/149 (0%)	Mean 0%	SD 0%	Total	1/149 (0.67%)	Mean 0.67%	SD 1.15%
*Spleen: Hemangioma	•••••	0/50 (00/)	0/50 (0%)	0/49 (0%)		0/50 (/0//)	0/50 (0%)	0/40 (09/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
*Spleen: Hemangiosarcoma		3/50 (6%)	1/50 (2%)	0/49 (0%)		5/50 (10%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	4/149 (2.68%)	Mean 2.67%	SD 3.06%	Total	6/149 (4.03%)	Mean 4.01%	SD 5.28%
*Spleen: Mast Cell Tumor Malignan	······································	0/50 (00()	0/50 /00/	0/40 (00/)		0/50 (00()	0/50 (00)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 342

Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
Spleen:								
Plasma Cell Tumor Malignar	nt	0/50 (0%)	0/50 (00/)	0/40 /00/)		0/50 (00/)	0/50 (00/)	0/40 (00/)
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:		• • • • • • • • • • • • • • • • • • • •	•••••			•••••		•••••
Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Stomach, Forestomach:					•••••			
Squamous Cell Carcinoma o	r Papillon	na Squamous						
-	-	0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%
Stomach, Forestomach:								
Squamous Cell Papilloma								
equamous con i apinoma		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	3/150 (2%)	Mean 2%	SD 0%
Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Stomach, Glandular: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*T								
*Testes: Adenoma								
		2/50 (4%)	2/50 (4%)	0/50 (0%)				
Overall Incidence	Total	4/150 (2.67%)	Mean 2.67%	SD 2.31%				
*Testes: Hemangiosarcoma		0/50 /00/	0/50 (00/)	0/50 (00/)				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
					•••••			
*Thymus: Thymoma Benign								
		0/49 (0%)	0/47 (0%)	0/47 (0%)		0/50 (0%)	0/47 (0%)	0/46 (0%)
Overall Incidence	Total	0/143 (0%)	Mean 0%	SD 0%	Total	0/143 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant								
		0/49 (0%)	1/47 (2%)	0/47 (0%)		0/50 (0%)	1/47 (2%)	0/46 (0%)
Overall Incidence	Total	1/143 (0.7%)	Mean 0.71%	SD 1.23%	Total	1/143 (0.7%)	Mean 0.71%	SD 1.23%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male	Female			
*Thymus: Thymoma: Benign, Malignan	nt, NOS	0/40 (00/)	4/47 (00() 0/47 (00()	0/50 (00/) 4/47 (20/) 0/46 (00/)			
Overall Incidence	Total	0/49 (0%) 1/143 (0.7%)	1/47 (2%) 0/47 (0%) Mean 0.71% SD 1.23%	0/50 (0%) 1/47 (2%) 0/46 (0%) Total 1/143 (0.7%) Mean 0.71% SD 1.23%			
*Thyroid Gland: Adenoma		0/50 (0%)	0/50 (00/) 0/40 (00/)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%			
*Thyroid Gland: C-Cell: Carcinoma							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%			
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	•••••	0/50 (0%)	0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)			
Overall Incidence	Total	0/149 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%			
*Thyroid Gland: Follicular Cell: Adenoma							
Overall Incidence	Total	0/50 (0%) 0/149 (0%)	0/50 (0%) 0/49 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 3/50 (6%)  Total 3/150 (2%) Mean 2% SD 3.46%			
*Thyroid Gland: Follicular Cell: Carcinoma		4/50 (00/)	0/50 (00() 0/40 (00()	0/50 (00/) 0/50 (00/) 0/50 (00/)			
Overall Incidence	Total	1/50 (2%) 1/149 (0.67%)	0/50 (0%) 0/49 (0%) Mean 0.67% SD 1.15%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/150 (0%) Mean 0% SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

Male Female \*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma (2%)(0%)(0%)(0%)(0%)(6%)**Overall Incidence** Total 1/149 (0.67%) Mean 0.67% SD 1.15% Total 3/150 (2%) Mean 2% SD 3.46% **#Tissue NOS:** Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 Mean 0% **#Tissue NOS:** Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Tissue NOS:** Plasma Cell Tumor Malignant (0%) (0%)0/50 (0%)(0%)(0%)0/50 0/50 0/50 0/50 **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% **#Tissue NOS:** Schwannoma Malignant 0/50 (0%)0/50 0/50 (0%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 Mean 0% SD 0% #Tongue: Fibroma (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 0/150 (0%) SD 0% SD 0% Total Mean 0% Total 0/150 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male		Female
#Tongue: Squamous Cell Carcinoma	1				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tongue: Squamous Cell Carcinoma	or Panillon	na Squamous			
oquamous oen oaremome	or rapilion	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Tongue: Squamous Cell Papilloma					
		0/50 (0%)	0/50 (0%) 0/50 (0%)	` ,	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Tooth: Odontoma					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%)
*Urinary Bladder:					
Hemangioma		0/50 (00/)	0/50 (00() 4/50 (00()	0/50 (00/)	0/50 (00/) 0/50 (00/)
Overell Institutes	Tatal	0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%)	Mean 0% SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (00/)	0/50 (00/) 0/50 (00/)	0/50 (00)	0.150 (001) 0.150 (001)
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date:04/29/2009

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
*Urinary Bladder: Plasma Cell Tumor Mal	lignant	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
#Uterus:	•••••							
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Uterus: Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Uterus: Hemangioma					•••••			
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Hemangiosarcoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 04/29/2009

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Male Female #Uterus: Leiomyoma 0/50 (0%)(0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% #Uterus: Leiomyosarcoma 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% #Uterus: **Polyp Stromal** 0/50 (0%)1/50 (2%)4/50 (8%) **Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 4.16% #Uterus: Sarcoma Stromal 0/50 (0%)0/50 (0%)Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% Sarcoma Stromal or Polyp Stromal 0/50 (0%)(2%)4/50 (8%)**Overall Incidence** Total 5/150 (3.33%) Mean 3.33% SD 4.16% **#Uterus:** Schwannoma Malignant (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/150 (0%) Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Version: May2009 Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

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			Male				Female	
#Vagina: Squamous Cell Carcinoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/150 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied